

	IFU Instructions for Use		Docu-Identifier IFU_SIVA-EN_A	
	SIVA		Revision A	Page 1/1

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History

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A	Initial version

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- IFU content (revision A, dated 2022-07-22)



Digital Cough Monitor and Accessories

Instructions for Use



valid for SIVA V1.0
with SIVA Smartphone Application V1.0
and SIVA Wearable V1.0

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1. Intended Use

SIVA is intended to be used in adult chronic cough patients (cough that lasts eight weeks or longer) to support the diagnostic process of the treating physician and to monitor treatment progress with objective cough frequency data mapped over time.

The SIVA Wearable (cough monitor) is a small device with various sensors (sound, vibrations), which is worn around the neck on a strap at chest level during the day. During sleep, the cough monitor is placed next to the bed and simultaneously charged by a charger. The sensors thus record the cough continuously.

SIVA also includes a smartphone application in which responses to daily diary questions are collected. The application transfers data from the smartphone to a data-secure cloud.

Requirements for the use of the cough monitor:

- Daily use of a smartphone with version
 - at least iOS 13, or
 - at least Android 10
 - Ability to operate simple smartphone applications
 - Ability to correctly plug in devices to power outlets
 - Willingness to wear cough monitor between bedtimes
- Willingness to store cough monitor on charger next to bed at bedtime

Contraindications:

- Use of other medical devices (e.g., portable oxygen concentrator, artificial pacemaker, implantable cardioverter defibrillator).
- Pregnancy

2. Safety Instructions

During the development of SIVA system, the safety requirements for medical electrical equipment according to the European standard EN 60601-1:2006+A12 and its use in a home healthcare environment according to the European standard EN 60601-1-11:2015 were taken into account, as well as the other applicable standards resulting from the characteristics of the system. (For information on electromagnetic compatibility, see chapter 8).

According to the risk analysis carried out during development, no unacceptable risks arise from the use of SIVA system.

Please report malfunctions, dangerous events in connection with the SIVA system or undesirable side effects occurring during use of the cough monitor or afterwards immediately to the SIVA Health service hotline.

The following residual risk exists in connection with the cough monitor:

- Although the cough monitor and its accessories have been designed and tested for skin-friendliness, it is possible that users (especially those with a corresponding predisposition) react with allergic signs (skin redness, rashes, itching) to contact with the neck strap textile or the housing of the wearable cough monitor. A slight reddening that disappears after a short time is harmless. In case of severe, permanent reddening or wounds, please contact the SIVA Health service hotline.

2.1 Cough monitor

- Do not drop the cough monitor as this may damage the device.
- Do not open the cough monitor or make any changes to the cough monitor (breaking open, painting) as this may impair the function of the cough monitor and - if the housing is open - an unpleasant, slight electric shock may occur.
- Do not operate the cough monitor in the presence of flammable anesthetics (e.g., in hospital) or other flammable substances (in signposted areas in danger of explosion, e.g., mines), as electrostatic discharges could lead to ignition sparks.
- Do not operate the cough monitor in an oxygen-enriched environment (e.g., oxygen tent).
- If the unit is damaged, store it out of reach of other people and pets and the SIVA Health service hotline. Collect any splintered parts of the housing to avoid the risk of small children or pets swallowing them. Do not touch the inside of the unit as this may cause an unpleasant, slight electric shock.

2.2 Charger

The product is intended for private, non-commercial household use.

- Do not put any metal materials like keys, rings, metallic phone cases etc. onto the charger
- If the cough monitor is not placed correctly in the center of the charger area, it may not properly charge and or heat up more than expected. In this case, remove the cough monitor from the charger, let it cool down, and put it back to the charger, paying special attention to place it precisely in the center of the charging area.
- Please use this product in the temperature range of 0-25 °C (32-77 °F), do not expose the product to water, fire, or overheated and lower temperature environments, as this may damage the product.
- Keep the charger out of range of children.
- Please use dry, clean, soft cloth to clean the product surface, do not use chemicals or soap.
- If the charger is damaged, do not continue to operate it and contact the SIVA Health service hotline.

WARNING

Do not place EC cards or similar cards with magnetic strips or magnetically sensitive objects on the product. The data on the cards may be damaged or deleted.

2.3 Power Supply Unit

The enclosed power supply is an approved product according to the European standard for medical electrical equipment (EN 60601-1), which protects you from the risk of electric shock with mains voltage when using SIVA Wearable.

The external power supplies have high power conversion efficiency; however, they do rely on convection cooling to the surrounding environment (air) to prevent overheating or excessive internal and external surface temperatures. Therefore, there needs to be adequate access to ambient air to ensure proper thermal performance of the power supply.

- Do not cover the power supply with blankets, clothing, pillows, or any other poor thermal conductor.
- Do not immerse the power supply in any liquid.
- Avoid dropping the power supply on hard surfaces.
- Avoid impacting the case of the power supply with any hard object.
- Use the proper input cord (desktop version) for the power supply.
- Use a proper mating connector for connection to the output of the power supply.
- Do not exceed the power rating of the product.
- If the power supply is damaged, do not continue to operate it and contact the SIVA Health service hotline.

WARNING

Do not use any power supply other than the one supplied with SIVA Wearable. The use of other mains adapters may cause overheating of the charger, undersupply of the charger, short circuits and, in the worst case, fatal electric shocks with mains voltage.

3. Product Description

The cough monitor (SIVA Wearable) is a small device with several sensors (sound, vibrations), which is worn around the neck during the day (sensors directed against the chest) - and stored next to the bed on the charger (see below) during bedtime.

If the cough monitor is charged overnight, it has sufficient energy and thus remains permanently switched on. The sensors thus record the cough continuously.

A) Cough monitor (see also chapters 8 and 9)

A1) Cough monitor – View of the top side / the side facing away from the body



A2) Cough monitor - view of the underside / the side facing the body with sensor / the side resting on the surface of the charger



B) Charger (see also chapter 7.1)

The charger is placed on the bedside table or next to the bed and charges the cough monitor while you sleep.

B1) Charger surface (charging contact surface to the cough monitor)



B2) Charger bottom surface (contact surface to bedside table or floor)

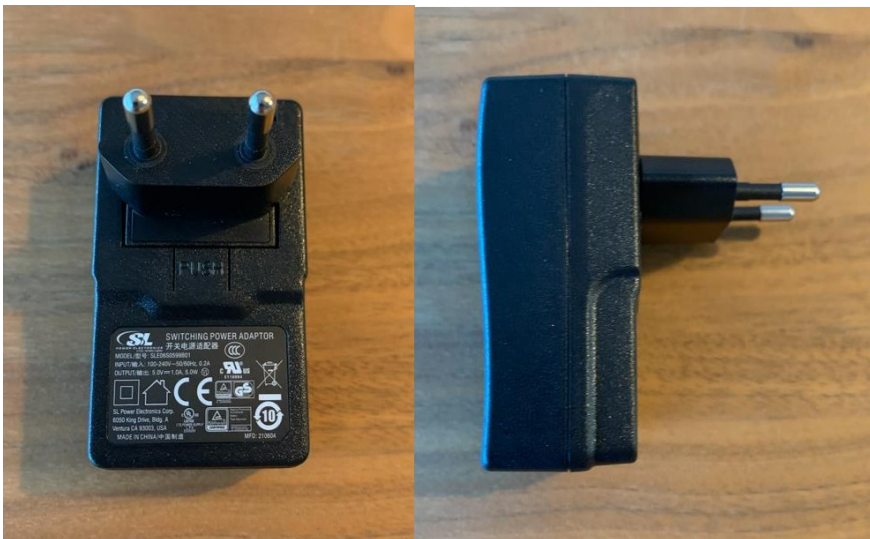


B3) Charger Accessories: USB Type A to USB Type C cable



C) Power supply unit (type of connector will vary based on country, see also chapter 7.2)

The power supply unit connects the charger to the mains socket or a multiple socket outlet.



D) Smartphone-Application

- for iOS (at least iOS 13)
- for Android (at least Android 10).

The procedures described in chapters 4. to **Error! Reference source not found.** cover the possible interactions with SIVA Wearable as well as the incidents during your use of SIVA system.

4. Preparation

Step 1 / Smartphone: Make sure you are connected to the internet with your smartphone. Download and install the SIVA Smartphone Application on your smartphone (unless you are using a preconfigured smartphone with the SIVA Smartphone Application already preinstalled).

Step 2 / Smartphone: Make sure that you have Bluetooth enabled on your smartphone and start the SIVA Smartphone Application. The access data will be provided by your healthcare professional (Login QR-Code).

Step 3 / Choosing a neck strap of proper length: From the selection of neck straps (small, medium, large), choose one that will place the device at a comfortable height on your chest.

Step 4 / Attaching the neck strap to the cough monitor: Push the end of the neck strap loop through the attachment loop of the cough monitor. Then move the end of the neck strap loop around device and pull it back (see sequence of pictures below).



Step 5 / Putting on the cough monitor: Attach the cough monitor around your neck as described in chapter 5.2 and wear it continuously - except when showering and swimming, in the sauna or during sporting activities where the device would disturb or hinder you - until you go to bed.



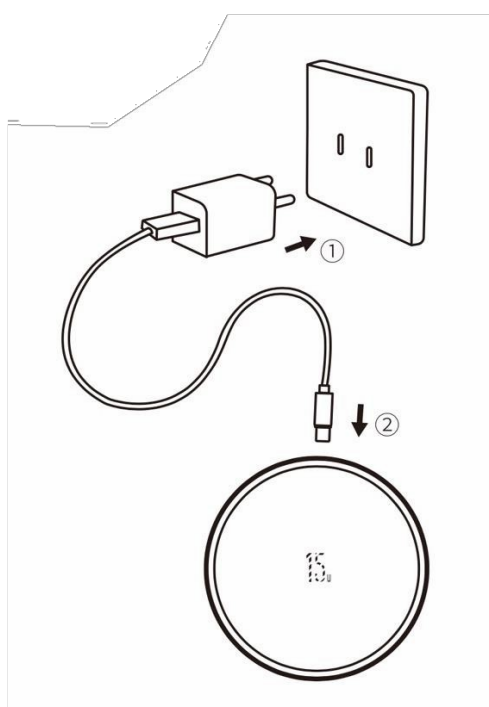
You will receive the cough monitor fully charged at the beginning - so it has enough energy until bedtime.

NOTE

To check if the cough monitor is working correctly double tap on its housing with a finger. This will enable the status indicator light for a few seconds. A blinking green light indicates that the device is active.

Step 6 / Charger & power supply (at home): Connect the charger to the enclosed power supply by with the enclosed USB cable

- Connect the larger connector (USB Type A) to the power supply.
- Connect the the smaller connector (USB Type C) to the charger (step (2) in illustration below).



Step 7 (at home): Position the charger on the bedside table (or on the floor if there is no bedside table right next to the bed).

- Plug the power supply unit into a wall socket or a multiple socket outlet.
- When the power supply is active, the LED indicator of the charger lights up green.

NOTE

Only use this charger to charge the cough monitor as other chargers may not fully charge the cough monitor.

Make sure that the charger is placed in an environment with a temperature of not more than 25 °C (77 °F) and avoid the charger to be placed in direct sunlight.

WARNING

Do not use any power supply other than the one supplied with the SIVA system. The use of other mains adapters may cause overheating of the charger, undersupply of the charger, short circuits and, in the worst case, fatal electric shocks with mains voltage.

Step 8 (at home): Store the cough monitor on the charger while sleeping. The regular charging process is described in chapter 5.6.

Step 9 (at home): Open the SIVA smartphone application regularly every evening to respond to daily diary questions.

5. Regular Use

5.1 Daily Use of the Smartphone

- Make sure that your smartphone has access to the Internet.
- Make sure Bluetooth is enabled on your smartphone

5.2 Putting the wearable cough monitor on

WARNING

- Before hanging the cough monitor around your neck, always make sure that the device is not damaged (cracks, missing parts). Especially if the cough monitor has been dropped on the floor.
If the device is damaged, store it out of reach of other people and pets and contact the SIVA Health service hotline. Collect any splintered parts of the housing to avoid the risk of small children or pets swallowing them. Do not touch the inside of the unit, as this may cause an unpleasant, slight electric shock.
- If you have open wounds in the neck or chest area that could come into contact with the cough monitor or strap, do not put it on as this could lead to impaired wound healing or infection.

Step 1: Make sure the bottom (side with label sticker) is facing the body.



Step 2: Open the magnetic lock of the neck strap and close it again behind your neck



Step 3: The cough monitor now lies over the garment on the chest.



Step 4: Now push the cough monitor through the neckline of your clothing. If it feels more comfortable, you can also wear it between two layers of clothing (e.g., between vest and shirt / T-shirt and jumper).



5.3 Wearing the Cough monitor

Wear the cough monitor during the day without interruption (except when showering and swimming, in the sauna or during sporting activities where the device would disturb or hinder you). During light sporting activities such as jogging, the cough monitor can usually be worn without any problems. If the cough monitor becomes wet with perspiration, simply clean it afterwards as described in chapter 6.1.

If you take the cough monitor off for showering, swimming, sauna or other sporting activities, always store it in a clean environment, away from high humidity and/or heat.

5.4 Taking off the Cough monitor

Step 1: Pull the cough monitor through the neckline of your clothes so that it is on top of your clothes.

Step 2: Open the magnetic lock of the neck strap and remove the cough monitor.

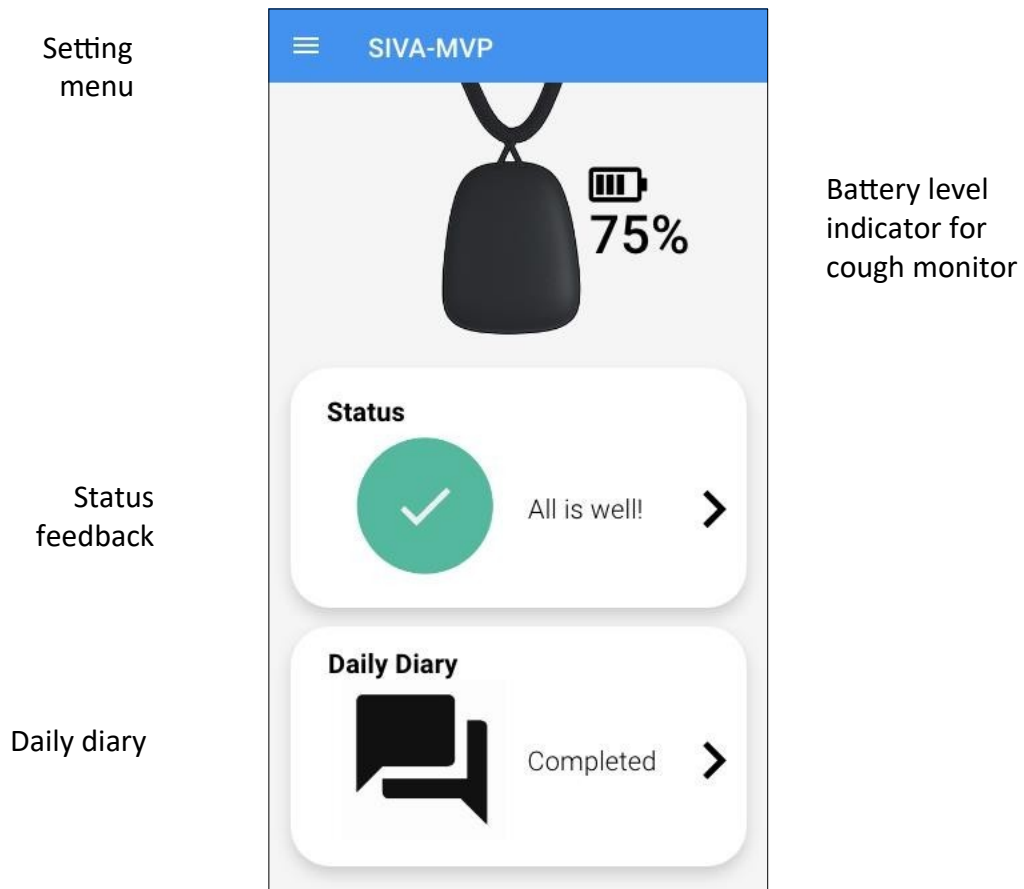
Step 3: Check the part of the body where the cough monitor is placed as well as the neck and throat area for skin intolerance. A slight reddening that disappears after a short time is harmless. In case of severe, permanent reddening or wounds, please contact the SIVA Health service hotline.

Step 4: Check the cough monitor and the neck strap for contamination and wetting by sweat and, if necessary, carry out cleaning as described in chapter 6.1.

5.5 Interaction with the Smartphone Application

5.5.1 User interface elements

When you open the smartphone application while no data transmission is active, the application will provide feedback if everything is operating correctly. If there is a need for action, the screen will show corresponding information



5.5.2 Status feedback

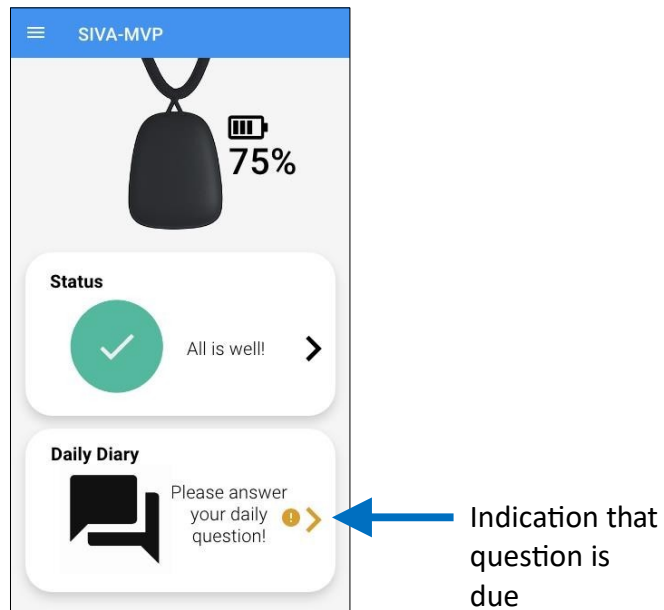
The status feedback indicates the overall state of the SIVA system. In case of an error, the feedback will be highlighted red to indicate the need for action. Tap on the status feedback tile to receive additional guidance how to resolve the error (see section 5.7).

The following status feedback options will occur during regular use:

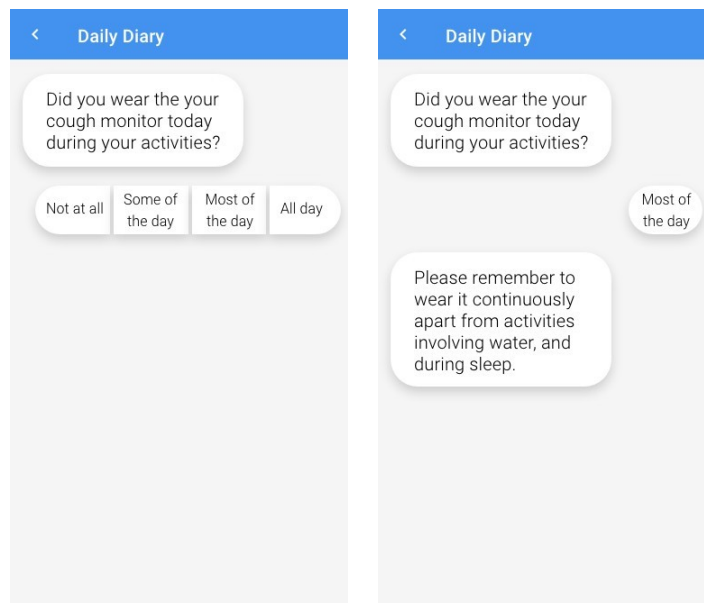
Feedback	Meaning
 All is well	All is well. Your data was successfully transmitted.
 Searching cough monitor	The smartphone application is connecting to your cough monitor.
 Communicating	The smartphone application is exchanging data with your cough monitor.
 Uploading data	Your cough monitor is uploading data to the cloud. Data transmission to the cloud will occur automatically when the wearable is on the charger and has been sufficiently charged for the next day.
 Checking Wi-Fi	Your cough monitor is checking that it can access the configured Wi-Fi to upload data to the cloud.
 Offboarding initiated	Your cough monitoring window has ended. Please place the cough monitor on the charger and check in again tomorrow evening to verify that all remaining data has been transmitted.
 Final data upload completed	Your cough monitoring window has ended and the final data has been successfully transmitted. Please pack up your cough monitoring equipment and return it following the instructions you received with the equipment.

5.5.3 Answering questions

You will be asked in the evening to confirm that you have been wearing the cough monitor on your smartphone. For this purpose, you will receive a notification message that reminds you to answer the question. The daily diary tile will indicate that answering the question is due:



Tap on the daily diary tile to answer the question:



After answering the question, tap on the arrow symbol in the upper left corner to return to the main screen.

5.6 Charging the Cough monitor (during bedtime)

- Put the cough monitor down immediately before going to bed and place it on the center of the charger that you have installed on the bedside table or next to the bed.
- Contact surfaces: place the bottom of the cough on the top of the charger.
- Positioning: Make sure that the cough monitor is placed flat in the center of the charger surface. When placed on the charger, the status indicator will show a green “breathing” light (i.e., slowly fading off and back on) for a few seconds to confirm that charging has started.



- The indicator light will turn off after a few seconds to not be disturbing during sleep.
- Leave the cough monitor on the charger for at least 6 hours so that it can fully charge.

NOTE

Make sure the unit is not accessible to pets or children when charging, as they may prevent proper charging by moving the cough monitor away from the charger.

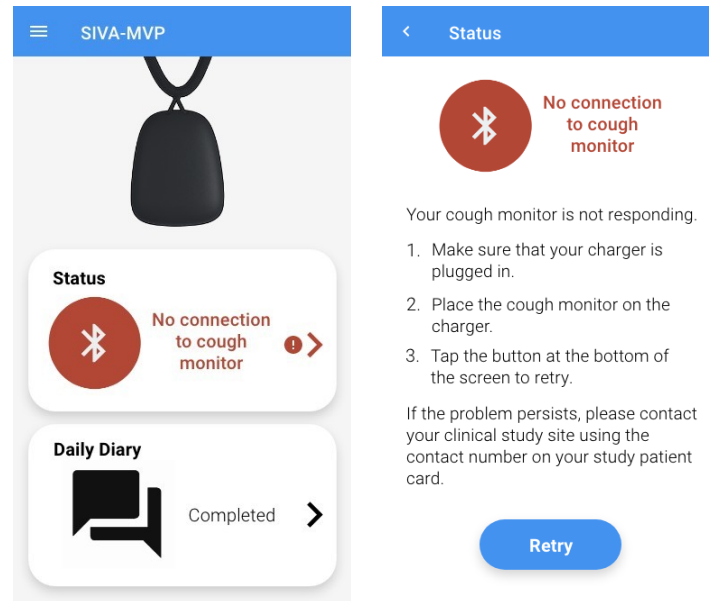
WARNING

- Before charging the cough monitor, always make sure that the charger is not damaged (cracks, missing parts). Especially if the charger has fallen on the floor. If the charger is damaged, store it out of reach of other people and contact the SIVA Health service hotline. Collect any splintered parts of the housing to avoid the risk of small children or pets swallowing them.
- Make sure that you only connect the charger with the enclosed USB cable and power supply, as electrical safety cannot be guaranteed with other components.

5.7 Troubleshooting

5.7.1 Error status feedback in the smartphone application

If the status feedback shows any of the feedback options listed below, tap on the status feedback tile to receive additional guidance, e.g.:



Follow the instructions in the status screen and tap the button at the bottom of the screen to retry the action that failed previously.

Feedback	Meaning
 No data uploaded	Your data was not successfully uploaded during the last 24 hours. Before you go to sleep, please make sure to place your cough monitor on the wireless charger and be sure your Wi-Fi router is working and in range of the cough monitor when charging.
 No Wi-Fi access	Your cough monitor was not able to access the Wi-Fi network. Please check that the Wi-Fi router is powered and turned on. If you changed the Wi-Fi router, use the application's settings menu to update Wi-Fi name and password.

Feedback		Meaning
	No communication to wearable	Your cough monitor is not responding. Make sure the charger is plugged in. Place the cough monitor on the charger.
	Missing permissions	Some of your smartphone settings have been changed and the SIVA application is not allowed to access Bluetooth anymore. Please make sure that the SIVA application has permissions to use Bluetooth. The retry button will take you to the smartphone settings menu.
	Bluetooth disabled	Some of your smartphone settings have been changed and the smartphone's Bluetooth functionality has been disabled. Please make sure that Bluetooth is enabled in the smartphone's settings menu.
	Smartphone without internet	Your smartphone does not have an Internet connection. Please check that the Wi-Fi router is powered and turned on. If you changed the Wi-Fi router, use the smartphone's settings menu to update Wi-Fi name and password.
	System error	A system error has occurred. Terminate the smartphone application and open it again.

If the guidance provided on the status screen does not help to resolve the issue, contact the SIVA Health service hotline.

5.7.2 Errors indicated by the cough monitor

- The status indicator on the cough monitor does not light up when the cough monitor is placed on the charger.



If the green light does not come on even though the cough monitor is on the charger,

- check that the charger, charging cable and plug are correctly connected to each other and to the socket.
- double tap the cough monitor with your finger to enable the status indicator again – if the green light starts “breathing” then, charging works as intended.
- and/or change the position of the cough monitor on the charger to make sure that it is oriented to fit between the guards and is

- The status indicator on the cough monitor blinks red



If the status indicator blinks red instead of “breathing” green after you have placed the wearable on the charger, the current device temperature is too high to charge the battery.

- Make sure that the charger is located in an environment not exceeding 25 °C (77 °F) and not placed in direct sunlight.
- Remove the cough monitor from the charger, wait for a few minutes to allow it to cool down and place it on the charger again. Make sure that the cough monitor is placed in the center of the charger.

If you cannot resolve the issue, contact the SIVA Health service hotline.

6. Cleaning and Maintenance

6.1 Cleaning and disinfecting the cough monitor

For cleaning the housing and the carrying strap:

- Clean the housing and the carrying strap as necessary (recommendation: at least every 2 days) with a cloth moistened with water or neutral detergent.
- Then rub the housing dry with a second cloth.

For disinfecting the housing:

- If you want to disinfect the unit, wipe the housing with a cloth moistened with ethyl alcohol (75 to 90%).
- Then allow the housing to air dry.

WARNING

- Do not use thinners, petrol, cleaning agents containing chlorine and other aggressive cleaning agents for cleaning, as the housing is not resistant to these agents. This may damage the housing, resulting in an unpleasant, mild electric shock.
- Do not clean the unit under running water, douse it with detergent or immerse it in cleaning agents, as this could damage the unit, causing an unpleasant, mild electric shock.

6.2 Cleaning the charger

- Clean the charger only with a lint-free cloth and do not use water, soap, or other cleaning agents.

6.3 Maintenance of the cough monitor and charger

6.3.1 General remarks

- Maintenance or repair must only be carried out by the manufacturer.
- If defective devices/connections/cables are suspected: do not use them anymore and do not try to repair them. In this case, please contact the SIVA Health service hotline.

WARNING

If a unit is damaged, store it out of reach of other people. Collect any splintered parts of the casing to avoid the risk of small children or pets swallowing them.

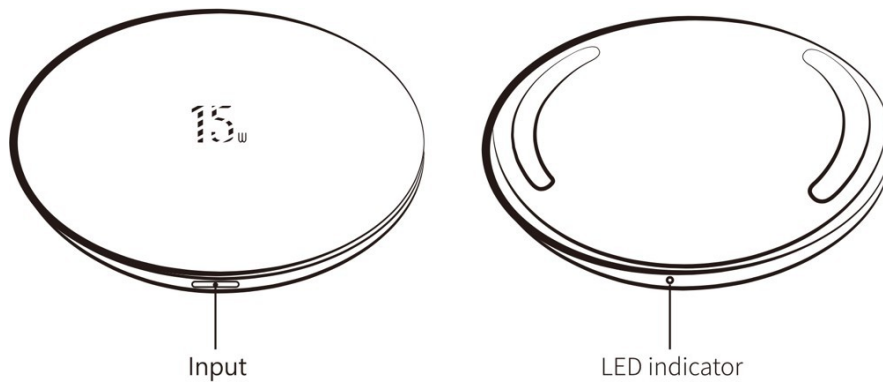
6.3.2 Replacement of a lost or broken cough monitor

If you contact the SIVA Health service hotline to report a broken or lost cough monitor, you will receive specific instructions how to set up your smartphone application with a replacement cough monitor.

7. Accessories

7.1 Charger (Induction)

The 'charger' (mentioned in the instructions for use) is an inductive charger model BSWC-P10C manufactured by Shenzhen Times Innovation Technology Co., Ltd.



Technical Data

Model: BSWC-P10C

Name: Baseus Simple Wireless Charger (Updated Version)

Material: Aluminum alloy + Tempered glass

Interface: Type-C input

Input Current: 5V==2A 9V==2A 12V==2A Max.

(It is recommended to use the QC3.0 adapter with power of 18W or above.)

Compatibility: Supports Qi-compliant wireless charging devices

Product Size: 93.0mm*93.0mm*6.4mm

Product Weight: 69.0g (without packaging)

Accessories: Type-C 1M Data Cable * 1

Expected life of environmental protection: 5 years

7.2 Power Supply Unit

The model reference of the power supply is SLE06S0599B01, manufactured by SL Power Electronics Corp.



Product features

FEATURES AND BENEFITS	
Medical & ITE Safety Approvals	CoC V5 Tier 2(2016)
2 x MOPP Input to Output Isolation	≤0.075W Standby Power
Suitable for Medical Equipment Up to Class BF ⁽¹⁾	4.2V to 12V Outputs, Up to 6W
Low Leakage Current ≤10μA	Up to 5,000m Operating Altitude
DOE Efficiency Level VI	Interchangeable AC Plugs or Fixed Blade Versions

Expected life of environmental protection: 10 years

8. Electromagnetic Compatibility

The electromagnetic compatibility of the cough monitor has been tested according to IEC 60601-1-2:2014 4th Edition (compliance with CISPR 11, Class B).

The cough monitor is suitable for operation in all environments, including the home environment.

Apart from communication with the smartphone via Bluetooth and the WiFi network for data upload to the cloud, the cough monitor uses RF energy only for its internal functions. Therefore, its RF emissions are very low and should not cause interference to electronic devices in the environment. However, the function of electronic devices that are susceptible to interference from Bluetooth or WiFi communication (frequency band 2402 - 2480 MHz) could be affected.

FCC application:

This device complies with Part 15 of the FCC Rules . Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, Pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

MPE Requirements

To satisfy FCC RF exposure requirements, a separation distance of 20 cm or more should be Maintained between the antenna of this device and persons during device operation.

To ensure compliance, operations at closer than this distance is not recommended.

9. Technical Data of the Cough monitor

Type	Wearable digital cough monitor
Device classification (according to IEC/EN 60601-1)	Type BF Applied Part Internal power supply Continuous operation
Approval	Exclusively for clinical investigation
Degree of protection	IP 57 Protected from limited dust ingress. Protected from immersion between 15 centimeters and 1 meter in depth.
Operating conditions	▪ Relative humidity ▪ Temperature ▪ Atmospheric pressure
	▪ 15% - 90% (non-condensing) ▪ 0 – 40 °C (32-104 °F) during wearing ▪ 0 – 25 °C (32-77 °F) during charging ▪ 70 kPa bis 106 kPa
Storage and transport conditions	
	▪ Relative humidity ▪ Temperature
	▪ 0% - 90% (non-condensing) ▪ -25 – 70 °C
Maximum enclosure temperature during operation	41 °C
Battery type	Rechargeable Lithium-ion Polymer battery pack
Expected battery life	At least 12 months
Battery operating time	Approx. 24 hours (may be shorter if exposed to loud environments for longer periods of time during the day)
Battery recharge time (in external charging station)	6h
Expected lifetime of the cough monitor	At least 12 months
Weight	25 g
Dimensions (W x H x D)	50 mm x 40 mm x 12.5 mm

Data Transmission

Frequency band 2401 – 2495 MHz

The cough monitor uses Bluetooth® low energy technology

Compatible with Bluetooth® 4.0 smartphones

Essential performance characteristics (according to IEC/EN 60601-1)

None

10. List of Symbols

Symbol	Meaning
	Degree of protection against electric shock: Type BF.
IP57	Protected from limited dust ingress. Protected from immersion between 15 centimeters and 1 meter in depth.
	Manufacturer
	Manufacturing date
	Consult instruction for use
[SN] 0001	Serial number
[REF] 0001	Type reference
	Warning
	Conformité Européenne (CE marking)
	Name and address of the Authorized Representative
	Temperature limits
	Humidity limits

Do not discard electronic products as unsorted waste.



Legal Manufacturer:



SIVA Health Ltd

Zurlindenstrasse 134

CH-8003 Zurich

www.siva-health.com

Service Hotline:

service@siva-health.com

+41 44 244 80 59

Certificate Of Completion

Envelope Id: 07D458ADBA58488F818C2B0AFA56C8A4

Status: Completed

Subject: IFU_SIVA-EN_A

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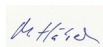
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Michael Häberli

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CEO

SIVA Health AG

Security Level: Email, Account Authentication
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Sent: 2022-08-04 | 16:46

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Alexander Duschau-Wicke

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Sent: 2022-08-04 | 19:13

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Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	2022-08-04 16:46
Certified Delivered	Security Checked	2022-08-05 08:44
Signing Complete	Security Checked	2022-08-05 08:44
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