PRODUCT DESCRIPTION

smartcorCONTROL consists of the corCONTROL sensor with integrated sensor technology, the corCONTROL unit, the corCONTROL smartphone app and the corCONTROL web app.

corCONTROL-Sensor XS/S	REF SCC0560 CE
corCONTROL-Sensor M/L	REF SCC0565 CE
corCONTROL-Unit	REF SCC0430 CE 0297
corCONTROL-App	REF SCC0590 CE 0297
corCONTROL-WebApp	REF SCC0620 CE 0297

INTENDED USE

smartcorCONTROL is designed to record a patient's cardiac activity over an extended period of up to 24 hours in a home environment, analyse the recordings for possible cardiac arrhythmias and display the results to medical experts for further investigation.

USER GROUP

smartcorCONTROL is suitable for persons aged 18 and over.

To use **smartcor**CONTROL, basic knowledge of how to use a smartphone is required.

SYSTEM REQUIREMENTS

Smartphone with Bluetooth function
Smartphone operating system: iOS > 13 or Android OS > 9 Internet connection (3G or WIFI)

PACKAGE INCLUDES

- corCONTROL sensor
- corCONTROL-unit
- USB docking station (data and charging cable)
- mesh bag
- Instructions for use

⚠ SAFETY INSTRUCTIONS

- If you use a pacemaker or other medical devices, consult your doctor before using this product.
- The product must not be worn during clinical examinations (e.g. MR/CT).
- Never wear the product within the deployment area of an airbag, as the deployment of the airbag can otherwise lead to injuries.
- Use the product only on uninjured skin.
- Keep the product out of the reach of children, as small parts in the product can cause choking if swallowed.
- Never attempt to disassemble the product or insert other objects into the product. This can lead to a fire or electric shock caused by a short circuit.
- Only authorised dealers or service centres may service/repair the product.
- The product must not be worn when swimming, bathing or showering.
- Do not use the corCONTROL unit if it overheats.
- Do not use the corCONTROL unit if it has been damaged or immersed in a liquid.
- Do not wear the corCONTROL unit while it is connected to a power source.
- ASSISTANCE

ASSISTANCE

Should you experience any problems while using **smartcor**CONTROL or if you have any questions about the product, please contact our support team via e-mail at 24.support@24sens.at or tap "contact support" in the corCONTROL app menu.
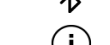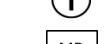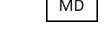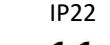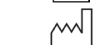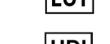
REPORTING NOTICE

All serious incidents occurring in connection with the smartcorCONTROL unit must be reported to the distributor, the authorised dealer and the competent authority.

DISPOSAL

Dispose of the individual product components in accordance with local regulations.

SYMBOL DESCRIPTION smartcorCONTROL

Symbol	Description
≡ -25°C/70°C	Temperature range (e.g. -25 °C to 70 °C)
0%/90%	Relative humidity range (e.g. 0% to 90%)
⊠	Don't dispose of in household waste.
🏭	Manufacturer
👁	Follow instructions for use
✶	Bluetooth
ⓘ	Information
MD	Medical device
IP22	IP protection class*
CE	CE marking (0297 – Notified body)
40	40 °C Laundry, delicate cycle
🧍	Body float (BF) **
⩗	Date of manufacture
REF	Reference number
NON STERILE	Not sterile
LOT	Lot number
UDI	Unique device identifier
⚠	Attention, important note!
☀	Protect from direct sunlight
⎓	Direct current DC

* Protection against finger contact and against foreign objects with diameters greater than 12 mm. There is also protection against water falling on it at an angle of up to 15°.
** The corCONTROL sensor is a BF type applied part which is connected to the body to record the ECG signal.

PRODUCT INFORMATIONS

CREATING A USER ACCOUNT   【1】
Install the corCONTROL app on your smartphone.
This is available in the App Store and Google Play Store.

When you start the corCONTROL app for the first time, click on "I'm new here" to create a user account. Then follow the further instructions.

If you have already created a user account, log in with your e-mail address and your chosen password.

Charge the corCONTROL unit using the USB docking station supplied. A full LED bar indicates that the corCONTROL unit is fully charged.

The product is now ready for recording.

START/STOP RECORDING   【2】
To start a recording, switch on the corCONTROL unit by briefly pressing the button and select "Connect corCONTROL unit" using the corCONTROL app on your smartphone.

Note: Make sure that the Bluetooth function is activated on your smartphone and ensure that the corCONTROL unit has sufficient battery power.

Now follow the step-by-step instructions.

Step 1:
By selecting "connect now", all corCONTROL units available in the area are displayed. Each corCONTROL unit has a unique identification number (UID – Unique Identifier) which is included in the packaging. Select your UID number and connect the corCONTROL unit to the corCONTROL app on your smartphone.

Step 2 – See the tutorial in the corCONTROL app:

Place the corCONTROL sensor around the abdomen, just below the chest, and close it. The logo should be on the left-hand side and the connection buttons should be facing forwards in the centre.

Attach the corCONTROL unit to the corCONTROL sensor using all four connection buttons. The corCONTROL unit's indicator light should be at the bottom and the switch-on button should be on the left-hand side.

Step 3:
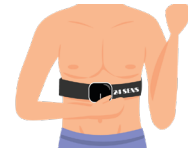Make sure once again that the corCONTROL sensor is correctly positioned. Then you can start recording! To do this, click on "Start recording". The message "Recording in progress" now appears in the corCONTROL app. Make sure that the status is "Connected to corCONTROL unit".

⚠️ Ensure that the corCONTROL sensor is positioned correctly and firmly secured to ensure good skin contact.

Possible Error Messages
"Electrode contact error": Check whether all pushbuttons on the corCONTROL unit are connected to the – corCONTROL sensor and that the corCONTROL sensor is correctly attached. To do this, follow instructions in Step 2.

⚠️ If the error message cannot be rectified by the measures mentioned above, please contact our support team via e-mail at 24.support@24sens.at or click on "Contact Support" in the corCONTROL app menu.

"Network Error": Check if you have an active internet connection on your smartphone.

ⓘ Please check the connection between the corCONTROL unit and the corCONTROL app occasionally while recording to ensure continuous recording.

Message Entry
Add comments during the recording using the "Messages" function to provide your doctor with important information when analysing your recordings. A detailed description of this function can be found int he instructions for use under corCONTROL app "New Message"

End Recording
To end a recording select "End recording".

DATA TRANSMISSION   【3】
Connect the corCONTROL unit to the PC or laptop using the USB docking station supplied. As soon as the corCONTROL unit is connected, an acoustic signal is emitted.

Open the corCONTROL webapp at www.24sens.com and log in with your existing user data.

ⓘ A detailed description of the corCONTROL webapp can be found in the corresponding operating instructions at www.24sens.com.

⚠️ The ECG recordings are saved on your corCONTROL unit. Please do not change the file names or the contents of the recording files. Manipulating these can lead to errors in the evaluation.

To share these with your doctor, select the desired recordings with the mouse cursor and drag them to the "click here or drag file here to upload" field.

EKG-Aufzeichnung hochladen

⬆️

Klicken Sie auf das Upload-Feld oder ziehen Sie Ihre EKG-Aufzeichnung (.QUS-Datei) in das Feld, um den Upload zu starten

Hinweis: Wenn Sie sich nicht sicher sind, wie Sie die EKG-Aufzeichnung von Ihrer corCONTROL-Unit auf Ihren PC übertragen können, lesen Sie bitte die Gebrauchsanweisung.

0%
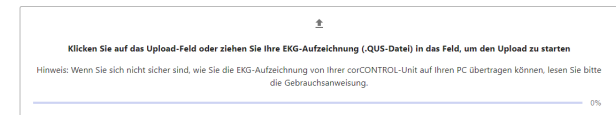
ⓘ Be careful when selecting the recording file you want to upload or share with your doctor. The file name of the recording is displayed in the corCONTROL app under "My Data".

CONNECTING WITH YOUR DOCTOR   【4】
Your doctor will invite you to share the data with him/her. You will receive an invitation link via e-mail, which you must confirm.
When you have successfully connected, the transferred recording files can be viewed, and the doctor can send you a message. You can find this message either under "My Data" or in the menu under "My Doctor"

corCONTROL App

"My Data"
In the "My Data" menu item, you can view the recordings you have already made.

The status of the respective recording is indicated by the following symbols:
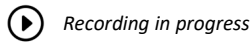
▶ *Recording in progress*

∿ *Recording has ended*

✓ *Recording has been uploaded and shared with the doctor*

✓✓ *Doctor has received the shared recording*

"New Message"
By clicking on a single recording under "My Data", you can use "New Message" to make one or more entries about your activities, any symptoms you have experienced and your well-being, and thus provide your doctor with important information.

To finish, click on "Save" in the top right-hand corner.

You can add or delete message entries until you have carried out the "Data Transfer" to your doctor. To do this, click on the desired recording and select "Edit" ("Pencill" symbol). You can now save an additional message or delete entries using the "Recycle Bin" symbol.

ⓘ Bei nachträglich hinzugefügten Notizen muss die dazugehörige Zeit eingegeben werden.

"Menu"
Under "Menu" you have the option to request the following information/functions:

- "My Account" – Details of your account, password change, log out:
- "My Doctor" – Contact details of your doctor
- "Instructions for Use" – Electronic instructions for use
- "Tutorial" – Instructions on how to tighten the corCONTROL sensor
- "Contact Support" – Contact for technical support from 24sens GmbH
- "Terms and Conditions" – General Terms and Conditions of
- 24sens GmbH
- "GDPR" – Information on the General Data Protection Regulation
- "On 24sens" – Information about the manufacturer and the product

DELETING RECORDINGS/DATA
If you want to cancel a recording, you must delete it in both the corCONTROL app and the corCONTROL unit.

Deleting in the corCONTROL App
To delete a recording in the corCONTROL app, press on and hold the corresponding recording in the "My Data" screen until the message "Do you want to delete this recording?" appears. Select the answer "Yes" to delete the recording from the corCONTROL app.

Deleting in the corCONTROL Unit
To delete a recording on the corCONTROL unit, connect it to your PC or laptop using the USB docking station supplied. Select the corresponding recording(s) on your PC or laptop and press the right mouse button → "delete".

ⓘ A Windows PC is required to delete the recording on the corCONTROL unit.

SOUND/LIGHT SIGNAL corCONTROL unit
The corCONTROL unit generates visual and acoustic signals that are used for information purposes and are described below:

Switching on
To switch on the corCONTROL unit, briefly press the button on the side. An acoustic signal is emitted, and the LED display shows the battery status.

Starting a recording
Three short beeps are emitted, and the LED display flashes faster.

Stopping a recording
A long signal tone is emitted, the LED indicator flashes more slowly.

Bluetooth connection interruption
If the Bluetooth connection is interrupted, four short beeps are emitted.

Switch off
After 20 minutes of inactivity, the corCONTROL unit automatically switches to sleep mode.

Memory full
When the memory of the corCONTROL unit is full, 3 beeps sound. It is no longer possible to start another recording.

ⓘ To clear the memory, either follow the description "Deleting in the conCONTROL unit" or press and hold the button on the corCONTROL unit for 10 seconds. This deletes all recording files saved on the corCONTROL unit.

PC/power source connection
When connecting to the PC, laptop or a power source, a short signal tone sounds.

Battery charge status
The charge status of the battery is displayed in the corCONTROL app. If the charge level is below 10%, an acoustic signal is also emitted.

OPERATING ENVIRONMENT FOR OPERATION
- The product must be used under the specified operating conditions. Otherwise, the service life of the product may be affected, or the product may be damaged.
- The product is intended for domestic use only.
- The product is not suitable for use in emergency situations.
- The product is not intended for use in hospitals.

INSRUCTIONS corCONTROL Unit

- The corCONTROL unit is powered by a rechargeable battery. The full performance of a new battery is achieved only after two to three complete charging and discharging cycles. Do not leave a fully charged battery connected to the charger, as overcharging can lead to a shortened battery lifespan.
- If a fully charged batter is not used, it will discharge over time.
- Storage outside the specified temperature range can reduce the performance and lifespan of the battery.
- Please observe the storage, transport and operating conditions specified in the instructions for use (See Table). A corCONTROL unit with a hot or cold battery may not function temporarily, even if the battery is fully charged.
- Charge the battery only with the USB docking station supplied.
- "Caution" – Improper handling of the battery used in the corCONTROL
- Unit can lead to fire or chemical burns. The battery may explode if damaged.
- The rechargeable battery in your device cannot be removed or replaced.
- Attempts to do so are risky and may damage the device.
- Disconnect the product or the associated USB docking station from the power supply before cleaning.
- The corCONTROL unit or the USB docking station can be wiped with a dry or slightly damp cloth.
- The corCONTROL unit has an average battery life of 24 hours.

INSTRUCTIONS corCONTROL Sensor

- Wearing the corCONTROL sensor can cause pressure marks on the skin. However, after removing the corCONTROL sensor, these are no longer visible after just a short period of time.
- Remove the corCONTROL sensor if it feels uncomfortable.
- To open the velcro fastener of the corCONTROL sensor, pull on the attached loop.

CLEANING the corCONTROL Sensor

- Make sure that you have removed the corCONTROL unit from
- the corCONTROL sensor before placing the corCONTROL sensor in the washing machine.
- The corCONTROL sensor can be washed at 40°C on a gentle cycle.
- Use the washing net supplied for washing to avoid damaging the corCONTROL sensor.
- The corCONTROL sensor can be washed up to 10 times.
- The corCONTROL sensor is not suitable for tumble drying.
- The corCONTROL sensor must not be ironed.

WARNING

⚠️ The use of accessories, transducers and cables other than those specified/provided by the manufacturer of this device may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and lead to incorrect operation.

⚠️ Portable high-frequency communication device (e.g. radio devices) including their accessories should not be used at a distance of less than 30 cm from the parts and cables designated by the manufacturer of the corCONTROL unit or the corCONTROL sensor. Non-compliance can lead to a reduction in the performance characteristics of the device

⚠️ The contact buttons of the corCONTROL unit may be connected only to those of the corCONTROL sensor and vice versa. Contact with conductive materials, in particular earthed metals, is not permitted.

⚠️ The contact surfaces of the corCONTROL sensor can exceed a surface temperature of 41 °C.

STORAGE, TRANSPORT AND OPERATING CONDITIONS

The corCONTROL unit and the corCONTROL sensor should not be exposed to direct sunlight during storage. Furthermore, the following ambient conditions must be observed:

	Storage and transport conditions	Operating conditions
Temperature min.	- 25 °C	10 °C
Temperature max.	70 °C	45 °C
Air pressure min.	700 hPa	700 hPa
Air pressure max.	1060 hPa	1060 hPa
Relative humidity min.	0 %	10 %
Relative humidity max.	90 %	95 %

TECHNICAL DESCRIPTION

corCONTROL unit:
Dimensiions: 60 x 45 x 10 mm
Weight: 22,6 Gramm
IP protection class IP22
4GB flash memory
BLE 4.0 (Bluetooth-Low-Energy)
Lithium polymer battery: 260 mAh; 3,7 V
corCONTROL-Sensor:
Size XS/S: 84 cm
Size M/L: 104 cm
The ECG signal is recorded at a sampling rate of 200 Hz (= 200 times per second). The presence of electromagnetic interference can affect the recording of the ECG signal.

CONNECTION TO THE SUPPLY NETWORK

nput voltage via supplied USB docking station: 4.40-5.25 VCurrent type: Direct current DC Current consumption: 500 mAThe corCONTROL unit has a service life of 500 charging cycles.

⚠️ Operation is only permitted with a CE-marked power supply unit, PC or notebook!

SPECIFICATION HIGH-FREQUENCY COMMUNICATION

High-frequency communication interface	Bluetooth® 4.0 Low Energy
Operating frequency	2400 MHz - 2483,5 MHz
Channel spacing	2 MHz
Modulation type	Gaussian frequency scanning (GFSK)
Effective radiant power	0,00086 Watt (=0,86 milliwatts)

INTERFERENCE EMISSION AND IMMUNITY TEST

The corCONTROL unit is designed to operate safely and effectively in the presence of nearby devices typically found in the home, workplace, retail stores and recreational venues, and does not interfere with their performance. Various electrical devices can cause interference in production environments. The corCONTROL unit records the input signals, uninterrupted, even during the interference, so there is no loss of data. The correct analysis of the HR intervals is restored after the interference has ended; no additional activity is required to be made on the corCONTROL unit.

Interference emission test	Conformity	Electromagnetic environment guidelines
RF interference emissions according to CISPR 11/EN 55011	Groupe 1	The corCONTROL unit uses RF energy exclusively for signal transmission via Bluetooth Low-Energy. Therefore, its RF emission is very low and it is unlikely to interfere with neighbouring electronic devices.
RF interference emissions according to CISPR 11/EN 55011	Class B	The corCONTROL unit is intended for use in home healthcare.
Harmonic currents EN 61000-3-2	not applicable	
Voltage fluctuations/flicker	not applicable	

Interference immunity test	Test level	Electromagnetic environment guidelines
Electrostatic discharge (ESD) EN 61000-4-2	±8 kV Contact ±2, ±4, ±8, ±15 kV air	The corCONTROL unit is suitable for use in a typical domestic or commercial environment.
Conducted disturbance variables	not applicable	The requirement does not apply to this battery-operated device.
Fast transient electrical disturbances/chest EN 61000-4-4	not applicable	The requirement does not apply to this battery-operated device.
Surge voltages EN61000-4-5	not applicable	The requirement does not apply to this battery-operated device.
Voltage dips, short-term interruptions and voltage fluctuations on power supply lines 61000-4-11	not applicable	The requirement does not apply to this battery-operated device.
Magnetic fields with energy frequencies /50/60 Hz) EN 61000-4-8	30 A/m 50/60Hz	
High-frequency electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM by 1 kHz	

Test frequency (MHZ)	Belt (MHz)	Service	Modulation	max. energy (W)	Distance (m)	Immunity test level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 to 470	GMRS 460, FRS 460	Pulse modulation 217 Hz	2	0,3	28
710	704 to 787	LTE Belt 13,17	Pulse modulation 18 Hz	0,2	0,3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDM 850, LTE Belt 5	Pulse modulation 217 Hz	2	0,3	9
870						
930						
1720	1700 to 1990	GSM 1800, CDMA 1900; GSM 1900; DECT; LTE Belt 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/G/N, RFID 2450, LTE Belt 7	Pulse modulation 217 Hz	2	0,3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9

PRECAUTIONARY MEASURES TO REDUCE ELECTROMAGNETIC INTERFERENCE

The corCONTROL unit fulfils the requirements of the international standards for electromagnetic compatibility. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must tolerate any interference received, including interference that may cause unwanted operations.

However, if it is determined during use that the corCONTROL unit is disturbed during an ECG recording, care should be taken to ensure that a sufficiently large distance from other devices or that these devices are switched off. Harmful interference can be detected by switching the potentially affected products off and on again.

ACCURACY QRS RECOGNITION

The accuracy of QRS detection for regular EKG signals (AHA and MIT-BHI database) is 99%. For ECG signals with pronounced interference signals (NST database), QRS detection is 80%.

## METHOD FOR CALCULATING THE HEART RATE Das The

process consists of pre-processing and peak detection.
The pre-processing essentially includes peak amplification, FIR filtering and outlier detection.
To identify heartbeats, a moving average is calculated using a window of 0.75 seconds on both sides of each data point. Regions of Interest (ROI) are marked between two intersections where the signal amplitude is greater than the moving average, the peak is then calculated as the maximum within this ROI. For further information see. 10.13140/RG.2.2.24895.56485

smartcorCONTROL
2023-10-10

PRODUKTINFORMATIONEN

INSTRUCTIONS FOR USE
IFU-**smartcor**CONTROL V.07
2023-10-10

## HANDLING USB Docking Station (Data- and Charging Cable)

The LED display of the corCONTROL unit must be aligned so that it is on the same side as the recess in the USB docking station. The corCONTROL unit must then be fully inserted into the USB docking station. You will feel and hear it click into place! When subsequently connected to the PC, laptop or a power source, you will hear a short beeping sound.
The procedure is as follows:

1 – Align the corCONTROL unit with the USB docking station
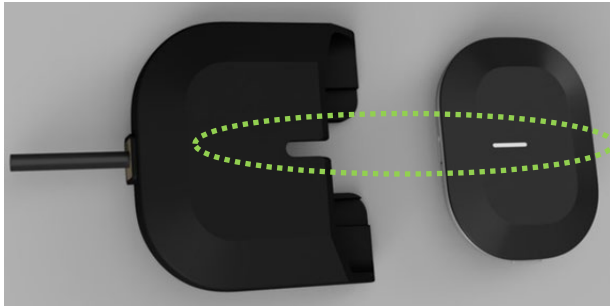
2 – Push in fully, you can feel and hear it click into place
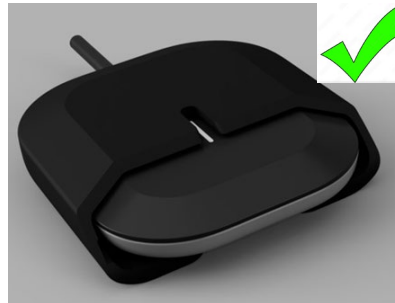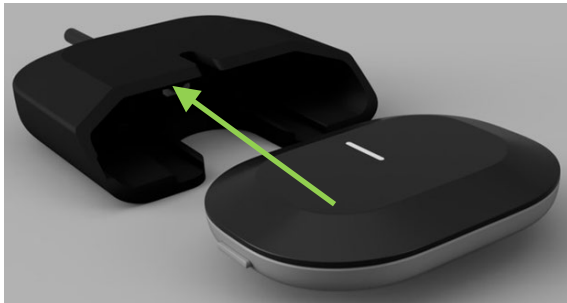
IT SECURITY MEASURES TO BE IMPLEMENTED

- Choose a secure password when you create a user account in the corCONTROL.app.
- Do not share your access data with third parties.
- Do not use public Wi-Fi when using the corCONTROL app.
- You can change your password at any time by logging out of the app and clicking on "Forgot Password" on the login screen.
- Do not hand over your smartphone if you do not want other people to have access to your corCONTROL app.
- Once your corCONTROL user account has been created the user data are entered and backend saved.
- If you get a new smartphone, you can login with your existing
- account details to access your data. If required, you have the option of having your user account deleted by 24sens employees. If you wish to physically delete the data, please contact us by e-mail at 24.support@24sens.at
- If you wish to upload ECG recordings, make sure that you do not make any changes to the recording file.
- Do not upload further/other files to the corCONTROL
- unit.
- Keep the corCONTROL app as up to date as possible.
- Do not hand over the corCONTROL unit to anyone else, as third parties can change/delete data on your corCONTROL unit.

MANUFACTURER INFORMATION

24sens GmbH | Millennium Park 15 | A - 6890 Lustenau
www.24sens.com | 24.support@24sens.at