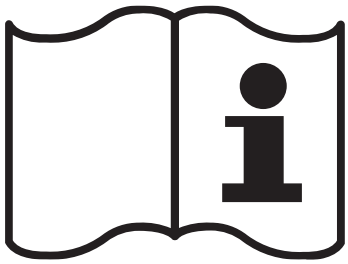
CORE-SAFE MEDICAL

CORE-SAFE ONE



INSTRUCTIONS FOR USE

TD01w-02-02-1-IFU-FV

Ed.1 Rev.0

Core-Safe Medical S.L.
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08302 Mataró, Barcelona (Spain)

EDITION REGISTER

EDITION	REVISION	DATE	REASON
1	0	25/05/2025	Initial edition

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1. GENERAL INFORMATION

1.1 ABOUT THIS MANUAL

This manual contains instructions necessary to operate the Core-Safe One monitoring device in accordance with its functions and intended use.

Ensure that all users of this device are properly trained and qualified, and with access to this manual

Before using the Core-Safe One, be sure to read carefully this user's guide. Failure to read and understand these instructions may lead to incorrect use of this device.

1.2 INDICACIONES FOR USE

1.2.1 INTENDED PURPOSE

The Core-Safe One is a wireless, non-invasive monitoring device based on the study of the cardiorespiratory system, providing information about the subject's cardiovascular state. The device allows the analysis of cardiovascular and respiratory stability, the identification of the blood pressure and the neuro autonomic state (NAS®) of the subject from the monitoring of the cardiac and respiratory sounds and movements and the electrocardiographic signal (ECG).

1.2.2 INDICATIONS

The Core-Safe One is designed to be used in combination with the display device and the Core-Safe Viewer software.

1.2.3 INTENDED USER

The Core-Safe One can be operated by the general adult public.

⚠ Core-Safe Medical does NOT certify the use of the Core-Safe One in a hospital environment.
The displayed indices by the Core-Safe One should NOT be used as a medical diagnosis.

1.2.4 INTENDED ENVIRONMENT

The Core-Safe One is designed for domestic use.

1.3 CONTRAINDICATIONS

⚠ Core-Safe One is NO intended for subjects below the age of 18 years

⚠ Core-Safe One should NOT be used under any circumstances while connected to the main power supply

⚠ Core-Safe One can NOT be used during a defibrillation

⚠ Subject population having at least one of the following conditions must be excluded from the use of the Core-Safe One:

- Allergy to adhesive patches
- Infection, inflammation or scarring that prevents proper placement of the adhesive patch

⚠ Subjects that suffer the following conditions

- Presence of pacemakers or defibrillators (ICD)
- Use of betablockers or antiarrhythmic medication
- Left upper lobe hypomobility

1.4 CONTACT

LOCATION

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(08302) Mataró, Barcelona, Spain

PHONE

+34 659 46 19 68

EMAIL

info@core-safe.com

1.5 WARRANTY

Core-Safe Medical warrants that the device is free from defects in material and workmanship under normal use of users and service for a period of 12 months from the date of delivery.

Core-Safe Medical warrants that accessories are free from defects in material and workmanship under normal use of users and service for a period of 30 days from the date of delivery.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with Core-Safe Medical. Repairs or replacement will be carried out, subject to the terms of this warranty.

Any warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner.

1.6 SYMBOLS

Symbol	Description
	Indicates the need for the user to consult the instructions for use
	Caution: A possible hazard may result in personal injury, and/or damage to the product if instructions are not followed
	Device manufacturer indicator
	Indicates that the device is not suitable for disposal through regular waste disposal methods

1.7 DISCLAIMER

Manufacturer reserves all rights. No part of this document may be reproduced or published, in any format without written consent of the manufacturer. The instructions in this manual are intended for trained users and/or authorized personnel to service and maintain the device.

The user assumes all responsibility for the proper use of the product and its components and accessories according to these instructions for use. Any use not specified in these instructions could cause damage to the product.

1.8 COPYRIGHT

2. TERMS AND DEFINITIONS

- **ACC**: Cardiorespiratory movements – Accelerometer signal
- **ADC**: Analog-to-Digital Converter
- **CBP**: Central Blood Pressure
- **ECG**: Electrocardiogram
- **HR**: Heart Rate
- **ICD**: Impantable cardioverter-desfibrillator
- **MIC**: Cardiac sounds – Microphone signal
- **NAS®**: Neuro Autonomic State
- **PCB** (Printed Circuit Board): Device motherboard
- **PNN**: Percentage of sucessive NN intervals
- **PTT**: Pulse Transit Time
- **Resp Rate**: Respiratory Rate
- **RMSSD**: Root Mean Square of Successive Differences
- **Subject**: Person on whom the device is used
- **User**: Person who uses the device

3. DEVICE DESCRIPTION

3.1 SYSTEM DESCRIPTION

The Core-Safe One is a device created for the monitoring of the cardiorespiratory system, the blood pressure and the neuro autonomic state (NAS®) of the subject.

Its use is based on the analysis of the cardiorespiratory activity through the acquisition and processing of the heart's electrical activity, referred to as ECG and cardiorespiratory rhythms and sounds.

Signals captured from the electrodes, a triaxial accelerometer, and two microphones, positioned on the upper chest, are transmitted to the analog-to-digital converter (ACD), which amplifies and digitalizes them. The device filters the data, rejects artifacts and uses advanced digital processing techniques to process the signals.

The processing allows for the extraction of features and parameters that facilitate the recognition of changes in the cardiorespiratory pattern to determine the heart rate, respiratory rate, blood pressure and neuro autonomic state (NAS®).

3.2 DEVICE PARTS BREAKDOWN

The Core-Safe One is a product that is used in combination with the Display Device and the software Core-Safe Viewer.

Figure 1. Core-Safe One assembly

3.2.1 Core-Safe One

The Core-Safe One is the main element of the set, which is formed by the external casing that contains the electronic PCB board and the battery. The PCB has connected a triaxial accelerometer and two microphones. The device features accessibility for a USB Type-C connector, required to recharge the battery.

The device features two lights on the lower part of the casing indicating the system activation and the wireless connection, shown in Figure 2. On the upper part of the casing there is the power button.

The posterior side of the external casing is connected with three snap buttons to a disposable adhesive patch, where the ECG electrodes are placed on. The disposable adhesive patch is the component in contact with the subject.

Figure 2. Lights in the outer casing.

3.2.2 Display Device

The Display Device is used in the Core-Safe One set. This device allows the visualization of the data using the software Core-Safe Viewer.

3.3 CORE-SAFE VIEWER

The Core-Safe Viewer is a software used to display the data collected by the Core-Safe One. It is previously installed in the operating system of the Display Device and contains all the features needed for the use of the product.

The software offers a real time display of the registered signal, with the ability to adjust various parameters to offer an improved visualization and/or resolve any incident that may occur while operating the device. The software also shows several indices and parameters extracted from the registered signals.

Figure 3. Overview of the Core-Safe Viewer

1. Signal graphing

Interactive section showing the real time registered signals; ECG, cardiac sounds (MIC) and cardiorespiratory movements (ACC). This section allows the display to be adjusted by zooming in on the signals and/or inverting the ECG.

2. Direct parameters

Board displaying, in real time, the parameters obtained directly from the registered signals, without additional processing.

- HR – Heart Rate, number of heart beats per minute.
- Resp Rate – Respiratory Rate, number of breaths per minute.

3. Indices

Board displaying the indices calculated by the device.

- NAS® (Neuro Autonomic State) – Marker to indicate the subject's probability of response to noxious stimulus via the sympathetic-parasympathetic balance based on their cardiorespiratory state, on a scale from 0 to 100. High values are indicators of high probability of response.
- CBP (Central Blood Pressure) – Central blood pressure obtained based on the cardiac electric signal and heart sounds.

4. Indirect parameters

Board displaying, in real time, the parameters obtained directly from the registered signals, based on additional processing.

- PTT (Pulse Transit Time) – Value related to the pulse transit time, calculated with the delay between the ECG and heart sounds.
- PNN (Percentage of successive NN intervals) – Parameter reflecting the activity of the autonomic nervous system on a scale from 0 to 100%.
- RMSSD (Root Mean Square of Successive Differences) – Parameter reflecting the influence of the autonomic peripheric nervous system in the cardiovascular system, in a scale from 0 to 200 ms.

The PNN and RMSSD values are displayed when the lower green bar is fully loaded.

5. Configuration buttons

- Button that allows the detention in a specific time window of the visualization of the signals without interfering with the register.
- Button to shut down the application and finalize the registration.

6. Informative section

Interactive section that allows the insertion of additional comments during the registration. It also contains the following additional information:

- Firmware and software version
- "*Saving*" – Additional text to indicate the registering state of the signal.
- "*Connected*" – Additional text that informs about the Core-Safe one correctly connected to the device.
- *"Rec time"* – Counter to indicate the total time of signal registration.

4. ASSEMBLY AND INSTALLATION OF THE CORE-SAFE ONE

4.1 DISPLAY DEVICE INSTALLATION AND PLACING

The Display Device must be positioned in the manner described in the manufacturer's instructions for use.

The Display Device should be positioned in a location with good visibility to ensure the proper interaction with the software Core-Safe Viewer.

> ⚠ The Display Device must be kept within 10 meters of the Core-Safe One device at all times.
> If the maximum range is exceeded, the device will disconnect and must be reconnected manually.

4.2 ASSEMBLING THE ADHESIVE PATCH

A new adhesive patch must be attached to the outer casing of the Core-Safe One by firmly pressing the three snap buttons. The wide part of the patch must align with the bottom of the Core-Safe One, as shown in Figure 4.

Figure 4. Placement of the adhesive patch on the Core-Safe One

> ⚠ It is only allowed to use the adhesive patch provided by Core-Safe Medical.

4.3 CORE-SAFE ONE INSTALLATION AND PLACING

To ensure optimal performance of the Core-Safe One, make sure the area of skin where the device is placed is clean and dry (without hair).

The protective film from the adhesive patch must be removed, avoiding contact with the adhesive surface.

The Core-Safe One must be placed in the upper part of the thorax, to the left of the sternum, as it is represented in Figure 5.

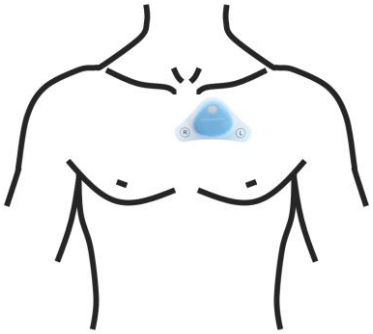

Figure 5. Placement of the Core-Safe One

5. DEVICE USE

These instructions provide a step-by-step guide on the procedure to make a correct use of the device. Its assembly and installation are needed beforehand, as described in section 4.

5.1 HARDWARE CONNECTION

Place the Core-Safe One in the position indicated in the section 4.2. Make sure the device is charged before its use.

5.2 HARDWARE POWER ON

Power on the Core-Safe One by pressing during 5 seconds the power button ⏻ on the upper part of the external casing. If the Core-Safe One has turned on properly, the lights will turn on automatically.

Turn on the Display Device and launch the Core-Safe Viewer application.

> ⚠ If the Display Device used was not provided by Core-Safe Medical S.L. the application Core-Safe Viewer must be installed.

5.3 CORE-SAFE VIEWER

5.3.1 EXECUTE THE SOFTWARE

Execute the Core-Safe Viewer application from the desktop of the Display device as shown in Figure 6.

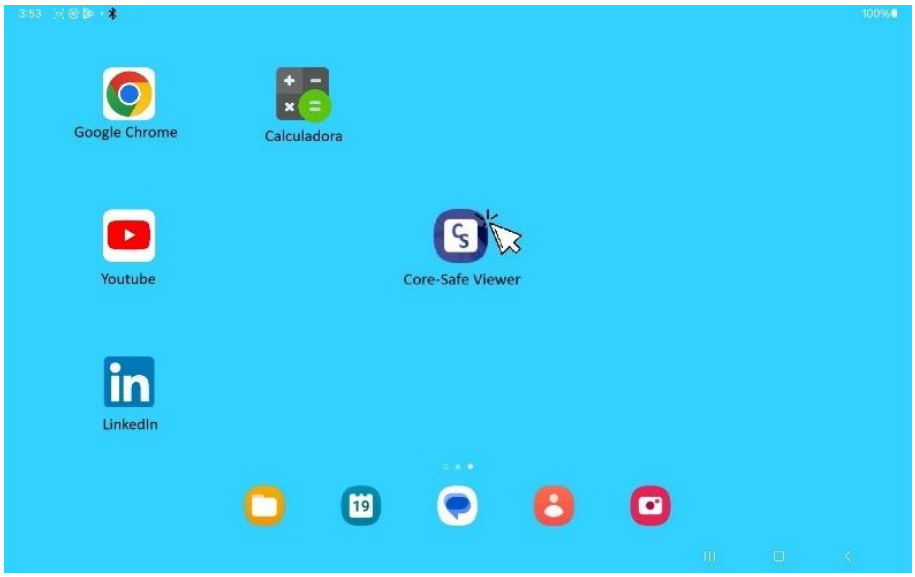

Figure 6. Execution of the Core-Safe Viewer

5.3.2 CORE-SAFE ONE DEVICE SELECTION

The selection menu of the Bluetooth device will open automatically. Select the corresponding Core-Safe One device and confirm its connection, as shown in Figure 7.

If no device appears available, follow the on-screen instructions and ensure that the Core-Safe One device has been properly powered on, as mentioned in section 5.2.

The software will run when a Core-Safe One device has been selected, starting with data logging.

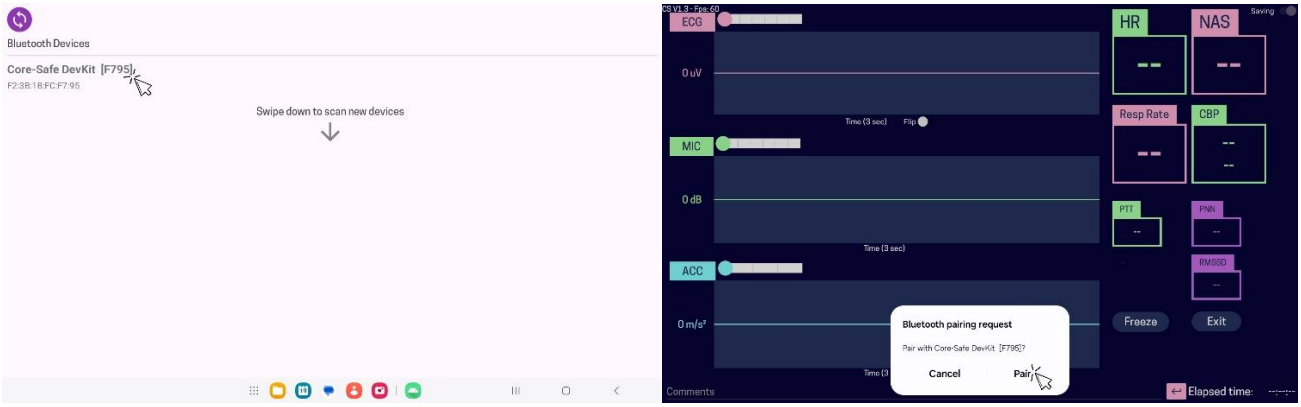

Figure 7. Selection of the Core-Safe One device

5.3.3 LIGHT INDICATION

The Core-Safe One uses LED lights to indicate its operational and connectivity status. The following section describes the different light patterns:

Activation Light

- ***No illumination:*** The Core-Safe One is powered off.
- ***Slow blinking:*** The device is powered on.
- ***Green light:*** The device is charging.

Wireless Connection Light

- ***No illumination:*** The Bluetooth system is turned off.
- ***Slow blinking:*** The Bluetooth system is active but not yet paired with the Display Device.
- ***Fast blinking:*** The Core-Safe One is successfully paired with the Display Device.

5.3.4 SIGNALS CHECKUP

The application will display in the top central section the three registered signals; ECG, MIC and ACC. Verify a proper visualization of the signals. If the display needs adjusting, review section 8 of this manual for troubleshooting.

5.3.5 SOFTWARE NORMAL OPERATION

While the software is operating, the registered data is automatically stored in the folder *"Internal storage\Documents\CoreSafe-Medical\REC"*.

5.3.6 EXIT AND SYSTEM SHUTDOWN

Once the need to monitor the subject is completed, you must press the *"Exit"* button located in section 5 of the software interface, defined in section 3.3, and confirm the disconnection, as shown in Figure 8. The Core-Safe One device must be removed from the subject's skin and the device must be turned off by holding down the power button ⏻ on the top of the external casing for 5 seconds. Separate the Core-Safe One from the adhesive patch for cleaning, as indicated in section 6.1, and for storage. The adhesive patch must be discarded.

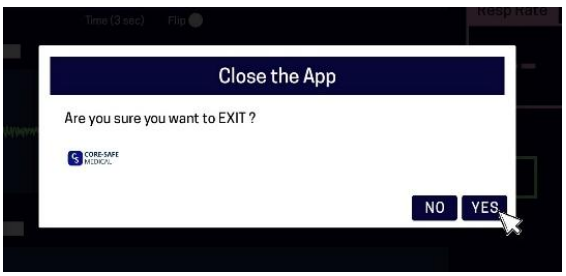

Figure 8. Disconnection of the Core-Safe One device

5.4 SOFTWARE FEATURES

The software presents interactive features that can be used by the user. None of these features interferes with the data recording, they are intended to improve the quality of the analysis or provide the user with visualization tools.

> ⚠ The interactive buttons "*Saving*" and "Exit" **DO** interfere in the data recording. Their deactivation will cease the data storing.

5.4.1 INDICES ABSENCE

The display of the indices will be possible when a quality signal is being recorded. The absence of the indices indicates that the signals are not being recorded properly. If the indices are not displayed within 30 seconds, the user should check the adhesion of the adhesive patch to the skin, without removing it, and the connection of the adhesive patch to the Core-Safe One device.

If this situation persists, the user should close the Core-Safe Viewer application and reconnect it following the steps in section 5.

5.4.2 SQI (Signal Quality Index)

The ECG channel has a dedicated Signal Quality Index which indicates the quality of the received signal. This feature is displayed below the ECG signal as a color-changing bar, as shown in Figure 9.

Acceptable SQI levels range from 100% to 70%, represented by a fully replenished green bar. SQI values between 70% and 50% are displayed in yellow. Any value below 50% will show the SQI bar in red, indicating poor signal quality.

Figure 9. SQI indication

5.4.3 ELECTRODE CONNECTION INDICATION

The software will show the text "Lead-Off" in replacement of the display of the signals, as shown in Figure 10, if the Core-Safe One is not correctly connected to the subject, ceasing the visualization of the signals. Review section 4 to ensure a proper connection.

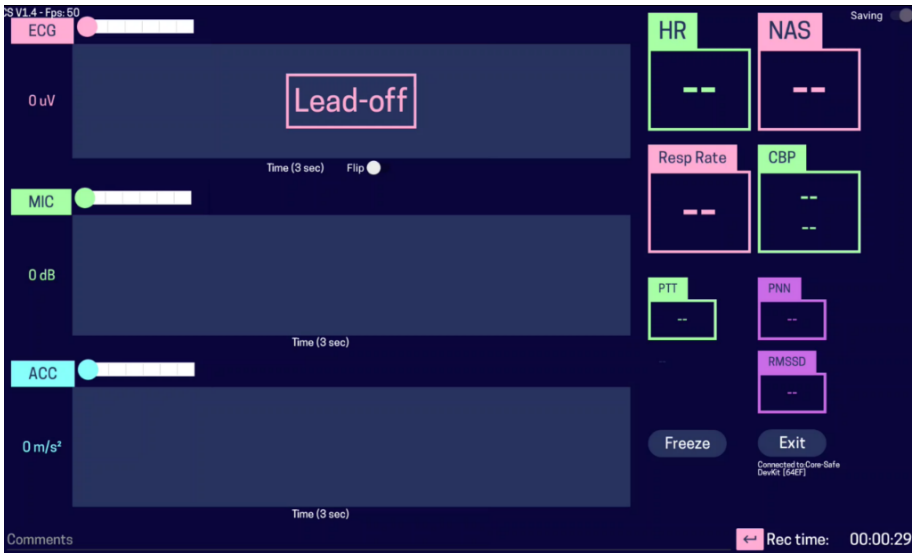

Figure 10. Lead off indication

5.4.4 CONNECTIVITY MEASUREMENT

The connectivity is assessed by the electrical impedance, which is continuously calculated. If sensor connectivity is low, a warning appears at the top of the interface, as shown in Figure 11.

If this situation persists, the user should review the placement of the Core-Safe One device on the subject.

Figure 11. Low connectivity warning

5.4.5 FREEZE AND EXIT BUTTONS

The default buttons are found in 5th segment of the interface, defined in section 3.3. The "*Exit*" button is on the right side, which will prompt the user to exit the program. The confirmation will end the recording.

The "*Freeze*" button is on the left side, which will temporarily stop the display of the signals, allowing a detailed analysis of a specific segment. In the frozen frame, two timestamps can be added in the viewer, using the arrows that appear at the top of the screen, to measure a specific time interval between events, as shown in Figure 12. The elapsed time is shown below each signal in seconds.

To resume real-time viewing, the "*Freeze*" button should be pressed. This button does not affect the recording of the values, it only alters its visualization.

Figure 12. Use of timestamps on the frozen viewer.

5.4.6 SAVING

The "*Saving*" button is found in the right upper side of the 6th segment of the interface, defined in section 3.3. The button is activated by default. The storing of the recorded signals ceases when the button is selected.

5.4.7 COMMENTS

The "*Comments*" bar is found at the bottom of the interface, which allows to comment on relevant situations or events during the recording process.

6. DEVICE MAINTENANCE

6.1 CLEANING AND POSTOPERATIVE MAINTENANCE

The device requires exterior cleaning after each use. Cleaning should be done with the device turned off and separated from the subject.

To clean the device, wipe it gently with a cloth, avoiding the USB port and sensors. If necessary, you can moisten the cloth with a mild soap solution or an alcohol-based solution. The device should be thoroughly dried with a dry cloth or air-dried before reuse.

6.2 CONSUMABLES AND REPLACEMENT PERIODOS

The adhesive silicone gel patch requires replacement after each use. Each use should not exceed the 24 hours.

6.3 MEMORY MONITORING AND MAINTENANCE

When the Core-Safe Viewer opens, several notices regarding memory management may appear.

- If the remaining memory of the Display Device is lower than 5 GB, a 'STORAGE WARNING' message is displayed, and the user is prompted to free up memory, shown in Figure 13 (Left). After clicking the 'EXIT' button, the Core-Safe Viewer will operate under normal conditions.
- If the remaining memory of the Display Device is lower than 0.5 GB, a 'INSUFFICIENT STORAGE' message appears, alerting the user that the data cannot be saved due to lack of memory and prompting him to free up memory, shown in Figure 13 (Right). After clicking the 'EXIT' button, the user may still use the Core-Safe Viewer to visualize the signals and the indices provided by the Core-Safe One, however, the data will not be stored.

To free up memory, the user should go to the folder where the Core-Safe Viewer saves the data (see 5.3.5), and delete other recordings. After freeing up memory, the Core-Safe Viewer needs to be restarted to reenable the functionality of data saving.

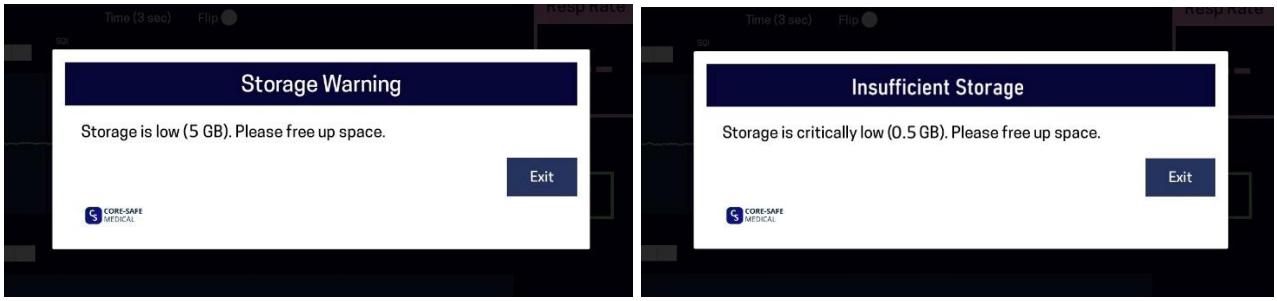

Figure 13. (Left) Warning of 'STORAGE WARNING'. (Right) Warning of 'INSUFFICIENT STORAGE'.

6.4 CORRECTIVE MAINTENANCE

If a malfunction is detected, the fault must be reported to Core-Safe Medical S.L., which will take charge of the situation.

> ⚠ Any action not authorized by Core-Safe Medical on the Core-Safe One device is prohibited.
> The Core-Safe One may only be reused after it has been reconditioned under the manufacturer's responsibility.

6.5 DISPOSAL AND RECYCLING

The Core-Safe One is subject to the European Union's Waste Electrical and Electronic Equipment (WEEE) 2012/19/EU Directive for recycling of electronic equipment.

7. STORAGE

7.1 STORAGE CONDITIONS

Store the Core-Safe One in accordance with the following considerations to prevent damaging and early aging of the device.

7.1.1 CLEANLINESS CONDITIONS

Make sure the device and the accessories have no dirtiness or debris on its surface as well as its connections. Refer to section 6 for cleaning instructions if needed.

7.1.2 HANDLING INSTRUCTIONS

When handling the Core-Safe One during storage, be sure to avoid dropping or bagging the device to prevent damage to its internal components.

7.1.3 PHYSICAL PROTECTION

Store the device and its accessories inside its box to protect it from physical damage.

⚠ The box contains the device's identification label so it should be kept with the device.

7.1.4 ENVIRONMENTAL CONSIDERATIONS

Do not store the Core-Safe One in direct sunlight or near sources of heat or moisture, such as radiators or humidifiers, to prevent damage to the device. Additionally, do not store the device near magnetic fields as this may affect its performance.

7.1.5 TEMPERATURE RANGE

Store the Core-Safe One and its accessories within a temperature range of 5ºC to 40ºC (41ºF to 104ºF) to prevent damage to its internal components.

7.1.6 HUMIDITY RANGE

Store the Core-Safe One and its accessories within a relative humidity range of 10% to 80% to prevent moisture damage to its internal components.

8. TROUBLESHOOTING

8.1 SOFTWARE INTERFACE

Signals display not achievable

- In case of not achieving a proper channel signal; ECG, MIC o ACC, change the scale using the sliding bar, found above the displayed signal, and/or invert the ECG signal using the button situated below the displayed signal.

Impedance constant warning

- In case of obtaining an unjustified constant warning for high impedance, proceed to check the placement of the Core-Safe One device (section 4.2). If the problem persists, disconnect the display device and repeat the connection of the Core-Safe One device.

Prolonged absence of the indices

- In case of noticing the indices absence for more than 5 minutes without apparent justification, proceed to check the placement of the Core-Safe One (section 4.2).

8.2 DEVICE MALFUNCTION

Microprocessor stops

- If the software seems frozen, close the application with the "*Exit*" button and turn off the Core-Safe One. The device has to be reconnected following the steps defined in section 5.

9. TECHNICAL SPECIFICATIONS

9.1.1 Core-Safe One

Physical Characteristics	Dimensions	52,5 x 47 x 17 mm
	Weight	25 g
	IP Rating	IP30
	Material	ABS + PC PANTONE 291C
Power	Input	Battery 5V DC
Connectivity	Bluetooth	BLE
Operating Environmental Limitations	Temperature Range	-20 to 60 ºC
	Humidity Range	10 to 80 % (non condensing)
	Pressure Range	86 to 106 kPa
Storage Environmental Limitations	Temperature Range	5 to 40 ºC
	Humidity Range	10 to 80 % (non condensing)
	Pressure Range	86 to 106 kPa
Limitations of use	Duration of use	3 days
	Expected lifetime	5 years

9.1.2 Index

HR (Heart Rate)	Indicator of cardiac activity.	30 to 240 beats/min
Resp Rate (Respiratory Rate)	Reflects the respiratory rhythm.	1 to 60 breaths/min
CBP (Central Blood Pressure)	Cardiac effort or stress.	• systolic – 90 to 220 mmHg • diastolic – 40 to 140 mmHg • mean – 50 to 120 mmHg
NAS® (Neuro Autonomic State)	Measure of the probability of response to noxious stimulus. It is an indicator of the sympathetic – parasympathetic balance of the autonomic nervous system.	0 – 100 (unitless) • 100 – high probability of response • 60 – moderate probability of response • 30 – low probability of response • 0 – no response
PTT (Pulse Transit Time)	Time for a pulse wave to travel between two arterial sites. It is related to the arterial pression and stiffness.	0 to 500 ms
PNN (Percentage of adjacent NN intervals)	Heart Rate Variability metric showing parasympathetic activity.	0 to 100%
RMSSD (Root Mean Square of Successive Differences)	Heart Rate Variability metric reflecting short-term parasympathetic modulation.	0 to 200 ms

9.2 Adhesive patch

Dimensions	112 x 63,5 x 6 mm	
Weight	10 g	
Material	PET	
Biocompatibility	Skin Irritation	☑
	Skin sensitization	☑
	Cytotoxicity	☑

9.3 Display Device

Hardware Characteristics	Power Input	5V DC
	RAM	4 GB
	CPU	2GHz – Octa-Core
	Screen Resolution	1200 x 1920 px – 16:10 ratio (~216 ppi density)
	Data Storage	64 GB
Software Characteristics	Software Version (Core-Safe Viewer)	v 1.2
	Software Version (Display Device)	Android v14