User Manual

CorX Smartwatch

(Model: SMD1800)

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1 CONTENTS

2 INFORMATION ABOUT THIS MANUAL

This documentation supporting the use of the device, is not intended for sales; its partial or total reproduction is forbidden without the express permission.
The information contained in this document is subject to change without notice for reasons of a technical trade.
It ensures, however, that this manual corresponds to your device delivered. The offsets will be included in new editions.
This manual provides information for the installation and proper use of the device and is recommended its accurate reading.
Failure, even partial, of the recommendations contained in it may lead to malfunction and damage to the device and void the warranty.

Writing conventions:

 ***NOTES***

NOTES HIGHLIGHT SOME IMPORTANT INFORMATION CONTAINED IN THE TEXT.

 ***CAUTIONS***

CAUTIONS MESSAGES APPEAR BEFORE SOME OPERATIONS AND IF THEY ARE NOT OBSERVED, MAY CAUSE DAMAGE THE DEVICE AND / OR ITS ACCESSORIES.

 ***WARNINGS***

WARNING MESSAGES INDICATES OPERATION OR SITUATIONS THAT MAY CAUSE RISK SITUATION FOR THE OPERATOR OR THE PATIENT IF THEY ARE UNKNOWN OR NOT DONE PROPERLY.

3 TECHNICAL FEATURES

The CorX Smartwatch(Model: SMD1800, Hearinafter shortened as CorX) are conform to the general rules on electrical safety of Electrical Appliances for medical use EN 60601-1, and also to detailed and collateral use applicable.

The manufacturer reserves the right to make product changes without notice according to the evolution of technology and standards.

3.1 General technical features

Power source (battery charger):	5V DC output
Battery type	Rechargeable lithium-polymer battery 180 mAh
Safety class:	II / BF
IP protection degree	IP 67
Condition of use	Spot checking
Device not suitable for use in the presence of a mixture of flammable anesthetic with oxygen or nitrous oxide.	

Expected Service Life: The expected service life is 2 years.

The mating cycle of USB cable is 1000 cycles.

3.2 Environmental characteristics

Operating temperature	+5 °C to +40 °C.
Storage temperature	-10 °C to +60 °C.
Operating and Storage Atmospheric Pressure	70 to 106 kPa
Relative humidity (non-condensing)	15% ~ 95%, without condensation

3.3 Technical features of the CorX

Technical specifications of the CorX

Physical

Weight	58 g
Dimensions	Dia 43 x 13.68 mm
Display	1.2” color active matrix TFT
Bluetooth	BLE 4.2
Sending duration	Real time

ECG

Lead type	Integrated ECG electrodes
Measurement mode	Episode
Sampling rate	250Hz
Sampling accuracy	24 bit
Display gain	10 mm/mV, 5 mm/mV
Sweep speed	25 mm/s
Bandwidth	0.5 to 40 Hz
HR measurement range	30 to 250 bpm
Accuracy	+/-2 bpm

SpO2

SpO2 range	70% to 100%
SpO2 accuracy (Arms)	80-100%: +/-2%, 70-79%: +/-3%
PR range	30 to 250 bpm
PR accuracy	+/-2 bpm
Wavelength / Power	660nm & 880nm / 6.5 mV & 9.5 mV

Technical specifications of the battery charger cable:

Weight	17g
Dimensions (charging head)	18.45x9x6.6 mm
Cable length	1 m

4 DESCRIPTION

CorX – The CorX is a class IIa medical device that satisfies the electrical safety requirements required by international standards.
The CorX is designed to perform exams with one derivation ECG, with a particularly fast procedure, which uses a graphical interface controllable tablet or smartphone.
This procedure records and collects all the information from while performs the data entry with personal data of the patient.

The CorX is a lightweight, portable health monitor for use in the home by lay-users. Instead of a customary box type unit, the CorX has been design as a wearable device in the form of a watch that can be used as a normal smartwatch (including social media notification, email notification, message notification) for measuring, displaying, reviewing and storing of multiple physiological parameters including ECG, heart rate, pulse oxygen saturation (SpO2), pulse rate, and monitor the physical activity by a pedometer and motion sensor. The proposed device, CorX, used is for spot checking of ECG, HR, SpO2, and PR in adult patients. This device is not intended to substitute for a hospital diagnostic ECG device or hospital pulse oxygen saturation.

The device is intended to be used in a home setting that is worn on the wrist as a watch that connects to an "app" on a smartdevice that can provide further functionality. The CorX is a watch that can display multiple physiological parameters including:

- ECG recording including QRS detection, VEB detection, and heart rate
- Functional pulse oxygen saturation (SpO2) by percent of saturation including pulse rate

Sensors and electrodes are contained in the housing of the watch that converts the information to electronic signals that are processed by the software to display different parameters. Measurement and recording of these parameters are stored in the watch that can be synced with the "app" on a smartdevice such as the user's phone. Information can then be reviewed as recorded by the watch and may also be transmitted through a "portal" for accessing information over the internet. This information can be viewed by a healthcare professional to see current or historical health information for a patient allowing more interaction to occur with the healthcare professional and patient.

Functionality of the device is integrated firmware and PCB contained in a housing that is slightly larger than a conventional watch with an adjustable band. The Saluber CorX is made from flexible plastic material that are common in other household and wearable products to provide comfort and flexibility to the user, e.g. similar to a Fitbit™ or Garmin® wearable device. A rechargeable lithium battery is contained in the device that can be charged through a standard USB 2.0/3.0 port. The smartwatch must not be charged while being worn; when the smartwatch is charging it goes into a particular state that is not available for use. The charge for continuous use is over many hours compared to intermittent use can be maintained for many days as the power consumption depends on use of physiological parameter monitoring.

The device does not contain alarms and is not to be used in emergency situations. Notifications and user programmable settings can be made which are indicated for personal health information. The device is not intended to be life-supporting or life-sustaining. The device is reusable by the patient and is non-sterile.

WARNINGS

The diagnosis of lower myocardial infarction without the use of precordial leads could cause false positives.

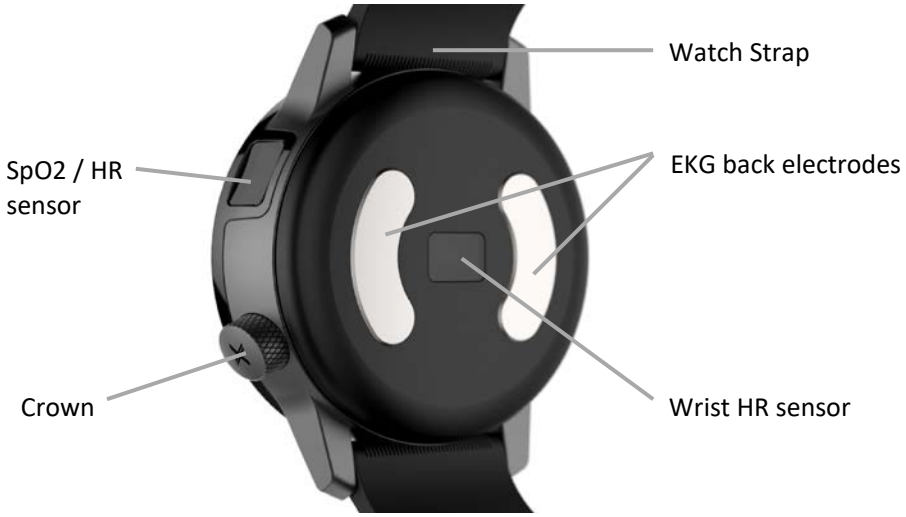
- The use of this device / system is not substitute for over methods of diagnosis.
- Do not change any medication or treatment without consulting your doctor. This device cannot detect a heart attack. If you are not feeling well, need consulting your doctor.
- The Telemedicine diagnosis may not be appropriate for certain diseases.
- The system is considered to be aimed at supporting actions "low level" as the cardiological screening, secure disposal, home monitoring.

- Do not use the device in a magnetic resonance (MR) environment.
- This device is not defibrillation proof.
- Do not allow the electrodes of the device to come into contact with other conductive parts (including earth).
- Do not store or use the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination, heavy dust; locations near to sources of water or fire; or locations that are subject to strong electromagnetic influences.

4.1 Basic Structure

CorX Smartwatch(Model: SMD 1800) is mainly comprised of LCD Display, Watch, Watch Strap, Rechargeable Lthium Battery and CorX SaluberMD app.

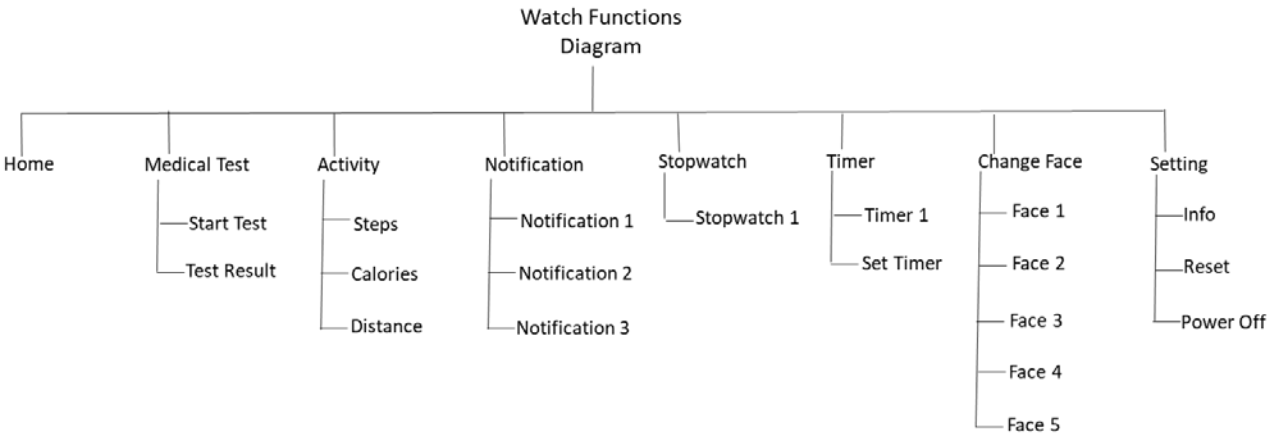
Front view



Rear view

Note:
- Swipe left / right to navigate different page features.
- Short tap / long tap on touch screen to select / confirm.

4.2 Watch Functions Diagram



4.3 Intended Use

The CorX is intended to be used for measuring, displaying, reviewing, and storing of ECG and oxygen saturation and pulse rate in a home or personal setting. The device is intended for adult use only. The physiological data is wirelessly transmitted to a remote server that can be reviewed by a healthcare practitioner.

5 FIRST USE

Check for signs of damage on the packaging, if they were not, remove the device from the case holding it firmly to void the risk of an accidental impact.

WARNINGS

If there are obvious signs of damage on the packaging NOT USE THE DEVICE and contact Customer Service of Saluber MD.

Do not dispose of the anti-collision packaging, as it could be reused during a possible transport and / or in case of inactivity of the device.

Please refer to the "How to Use" before turning on the device and:

- Check the parts and accessories, as listed in Section 7;
- Ensure that the power supply network respects the standards shown in this manual;
- Make sure that the electrical system is made in compliance with applicable standards;
- Place the appliance stably and safely;
- Do not use the device in potentially explosive environments (ex. the presence of anesthetic gases) or in environments with high humidity (see table Technical Features);
- Use the device at a safe distance (at least 3 meters) to shortwave or microwave devices, in order to avoid interaction.

WARNINGS

Please remember to read carefully this manual and the contraindications contained in paragraph 12.

CAUTIONS

Before using the device for the first time, you must charge the battery. Refer to steps RECHARGE THE BATTERIES.

5.1 Charging the battery

1. Plug the small end of the USB cable into the charging port of your device.
2. Plug the large end of the USB cable into a USB charging port.
3. Charge the device completely.

WARNINGS

Do not place the small end of the USB cable on any metal surfaces when its large end is plugging into a USB charging port. Otherwise this may damage your charger or device.

6 SANITATION OF THE DEVICE

The device must be sanitized / disinfected periodically (see table maintenance).

- Unplug the charger;
- Do not use compressed air or nebulized products; a possible infiltration of any fluid may compromise the device;
- Don’t try to open the device and remove the material penetrated in case of accidental infiltration of liquids or extraneous materials inside the casing, but please contact the technical service and not use the device;
- Cleaning should be carried out using a not abrasive cloth with not corrosive sanitizers, rubbing without excessive force.

CAUTIONS

Sanitize / disinfect the device with non-alcoholic products.

7 LIST OF ACCESSORIES

Battery charging cable

P/N	DESCRIPTION
J5301-0025-01-AA	CorX Charging Cable

WARNINGS

The use of not original accessories may be a source of serious risks for PATIENT OR OPERATOR.

CAUTIONS

The use of not original accessories may damage the DEVICE.
Keep away from metal contact when the USB is plugging on any devices to prevent short circuit

NOTE

The use of not original accessories will void any form of WARRANTY Product.

8 WORKING ENVIRONMENT AND STORAGE

The device cannot be used in environments that aren't conform to the specifications given in paragraph ENVIRONMENTAL CHARACTERISTICS (3.2)

In accordance with CEI EN 60601-1-11 sections 1.1 and 3.2 can be used:

- PROFESSIONAL HEALTHCARE STRUCTURES (hospitals, medical offices, surgical centers, dental clinics, birth centers, health care facilities, health care facilities for multiple treatment and emergency, medical services);
- HOME HEALTH ASSISTANCE (home / place in which a patient lives or other places where there are patients).

WARNINGS

PREVIOUS POINT LIMITATION: THE DEVICE CANNOT BE USED IN MOTION (EN 60601-1-11 Point 3.6)

8.1 Tables guide of ELECTROMAGNETIC COMPATIBILITY

In accordance with CEI EN 60601-1-2, section 6.8.3.201 (letter "a" and "b") provides information on various aspects of electromagnetic compatibility and in particular the methods of carrying out the type tests carried out and the characteristics required for the environment in wichthe device can be used.

Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. ***WARNINGS*** The user must ensure that it is used in that specific environment. Failure to observe may generate risk situations.		
Emissions Test	**Conformity**	**Electromagnetic Environment - Guidance**
CEI EN 55011 Emissions RF	compliant (group 1)	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
CEI EN 55011 Emissions RF	compliant (class B)	The device is suitable for use in all rooms including domestic establishments and those directly connected to a power grid at low voltage which supplies buildings used for domestic purposes.
CEI EN 61000-3-2 Harmonic Emissions	compliant (class A)	
CEI EN 61000-3-3 Emissions ofvoltage fluctuations/flicker	compliant	

This first table (rif.201 of the standard cited above) realizes the aspects related to the emissions of the device, and all the possible noise or interference generated by the device that could disturb other electronic equipment more or less close.

Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below.  ***WARNINGS*** The user must ensure that it is used in that specific environment. Failure to observe may generate risk situations.			
Immunity Test	**Test Level IEC 60601**	**Conformity**	**Electromagnetic Environment - Guidance**
CEI EN 61000-4-2 Electrostatic discharge (ESD)	±6 kV in contact	compliant	Floors should be made of wood, concrete or ceramic. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV in air	compliant	
CEI EN 61000-4-4 Electric fast transient/Burst	±2 kV for the power line	compliant	The quality of the network voltage should be that of a typical commercial or hospital environment.
CEI EN 61000-4-5 Extra Voltages	±1 kV in differential mode	compliant	The quality of the network voltage should be that of a typical commercial or hospital environment. (applies to the step of charging the batteries)
	±2 kV in common mode	compliant	
CEI EN 61000-4-11 Voltage dips, short interruptions and voltage variations on power supply input lines.	0% Ut (dip 100%) for 0,5 cycles;	N.A.	Device powered only by battery
	40% Ut (dip 60%) for 5 cycles	N.A.	
	70% Ut (dip 30%) for 25 cycles	N.A.	
	0% Ut (dip 100%) for 5 seconds	N.A.	
CEI EN 61000-4-8 Magnetic field with network frequency (50 Hz)	3 A/m	compliant	The magnetic fields should have levels characteristic of a typical location in a typical commercial or hospital
Note: Ut is the network voltage before the application of the test level.			

The second table (rif.202 of the standard cited above) concerns the various tests of immunity to interference, highlighting the type and levels of the test, in addition to reporting important observations and recommendations for the user. The immunity is the ability of a device to not be disturbed by electromagnetic disturbances in the environment of use, whether they are transmitted by cable (ducts) than in air (radiated).

<table>
<tr><th colspan="4">Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The device is intended for use in the electromagnetic environment specified below.

WARNINGS
The user must ensure that it is used in that specific environment.
Failure to observe may generate risk situations.</td></tr>
<tr><th>Immunity Test</th><th>Test Level
IEC 60601</th><th>Conformity</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>CEI EN 61000-4-6
RF conduct</td><td>3 Veff
from 150 KHz to 80 MHz</td><td>compliant
(3 V)
(applies to the step of charging the batteries)</td><td rowspan="2">Communications equipment to portable and mobile RF should not be used closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1{,}2\sqrt{P}$
$d = 1{,}2\sqrt{P}$ (from 80 MHz to 800 MHz)
$d = 2{,}3\sqrt{P}$ (from 800 MHz to 2,5 GHz)
where P is the maximum rated output of the transmitter in watts (W) according to the transmitter manufacturer andd is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic survey of the site, may be less than the compliance level in each frequency range b.Interference may occur near of equipment marked with the following symbol:
  </td></tr>
<tr><td>CEI EN 61000-4-3
RF radiated</td><td>3 V/m
From 80 MHz to 2,5 GHz</td><td>compliant
(3 V/m)</td></tr>
<tr><td colspan="4">Note:
(1) At 80 MHz and 800 MHzapplies the higer range frequency.
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">a) The intensity field from fixed trasmitterssuch as base stations for telephones radio (cellular and cordless) and land mobile radios, amateur radio, AM and FM radio transmitters and TV transmitters can not be predicted theoretically with accuracy.To assess the electromagnetic environment due to fixed RF transmitters, you should consider an electromagnetic study of the site. If the measured field strength in the place where the device is used exceeds the applicable RF compliance level above, should be placed under observation normal operation of the device. If abnormal performance is observed additional measures may be necessary such as reorienting or device location.
b) The field strength in the frequency range from 150 kHz to 80 MHz should be less than 3 V / m.</td></tr>
</table>

Thev previous table (rif.204 of standard cited) and one below (rif.206) concern the noise generated by RF transmitters (ex mobile phones) and indicate the minimum distance to be maintained between an RF transmitter and the device, as well as how to calculate this distance.Obviously, these directions are valid for any device generating significant RF power, such as equipment for diathermy (Radar and Marconitherapy, that is at 2.5 GHz and 27 MHz also produce several hundreds of watts).If it is true that these apparatuses are not constructed to radiate with Antenna in space, it is true that even if the coupling with the patient was optimal (99%), the remaining part would still dispersed in air, and 1% to 500W is equal to 5W. This power at 27 MHz leads to calculate a minimum distance of about 2.7 meters. ***These considerations lead to the conclusion that the use of rails for Marconi and / or radar therapy is not compatible with the use of the device.***

Recommended separation distances between portable and mobile communications equipment and the device.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are under control.The user can help prevent electromagnetic interference by maintaining a minimum distance between communication devices portable and mobile RF (transmitters) and the device as recommended below, in relation to the maximum output power of the communications equipment.			
Specified maximum output power of the transmitter W	**Separation distance to the transmitter frequency (m)**		
	from 150 KHz to 80 MHz $d = 1{,}2\sqrt{P}$	**from 80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**from 800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,20	1,20	2,30
10	3,80	3,80	7,30
100	12	12	23
For transmitters specified for a maximum output power output is not shown above, the separation distance recom-date d in meters (m) can be calculated using the equation applicable to the frequency of the transmitter, where P is the maximum power rating of 'output of the transmitter in watts (W) according to the transmitter manufacturer. Note: At 80 MHz and 800 MHz frequency range applies is the higher. These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects and people.			

8.2 SDoC of FCC (Federal Communications Commission)

Declaration of Conformity

Trade Name : CorX Smartwatch
Model : SMD 1800
Responsible party : SaluberMD LLC.
Address : 209 Capitol Street, Charleston WV 25301,USA

Telephone Number :1-416-573-2307

9 ORDINARY AND EXTRAORDINARY PREVENTIVE MAINTENANCE

CLEAN AND CARE

- Regularly clean your strap and wrist—especially after working out or sweating. Rinse the strap with water. Do NOT use hand soap, body soap, dish soap, hand sanitizers, cleaning wipes or household cleaners, which could get trapped beneath the band and irritate skin. Instead use a soap-free cleanser to clean the wristband. Always dry the band well before putting it back on.
- For tough spots, stains or buildup on your strap, scrub with a wet, soft-bristled toothbrush.
- Prolonged rubbing and pressure may irritate the skin, so give your wrist a break by removing the strap for an hour after extended wear.

Other Tips

- If you have eczema, allergies or asthma, you may be more likely to experience a skin irritation or allergy from this device.
- Whether you have the conditions above or not, if you start to experience redness or skin irritation on your wrist, remove your device. If symptoms persist longer than 2-3 days of not using your device, contact a dermatologist.
- If you sweat for more than two hours while wearing your device, be sure to wash your strap and your wrist using the directions above to avoid skin irritation.

PREVENTIVE MAINTENANCE: to ensure the correct operation and safety of the user and the operator, you must subject the device to some checks and periodic inspections.

Therefore it is important to check the device by authorized staff with maximum intervals of 12 months or if in case of any malfunction.

BATTERY REPLACEMENT:

WARNINGS

The battery must / may be replaced after 300 charge cycles or after 24 months use.

To replace the CorX battery contact the technical support Saluber MD.

ORDINARY MAINTENANCE: the operator must check the wear of patient electrodes through the time, and promptly replace them (by authorized dealer), if there is a need.

WARNINGS

In case of evident abnormalities, do not use the device.

EXTRAORDINARY MAINTENANCE: the extraordinary maintenance must be realized by internal staff of Saluber MD or qualified personnel, trained and authorized by Saluber MD. The manufacturer is committed

to providing circuit diagrams, parts lists and anything else necessary to calibration and repairs the device, only to a qualified and authorized personnel in those activities.

WARNINGS

All interventions must be recorded in Table sheet machine in order to ensure the maximum safety of the device.

WARNINGS

This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device.

WARNINGS

Please placed out of children's and pets reach to prevent device damage.

NOTE

The following table contains the summary of the maintenance operations

TYPE	*ACTION*	*AUTHORITY*	*FREQUENCY*
Preventive	Visual inspection of the integrity of the charging cable (if there is deterioration contact the technical support service)	Operator	Weekly
Preventive	Cleaning the inside, verification of functionality, review and calibration	Authorized laboratory	Annually
Preventive	Instrumental tests of currents leakage and electrical safety	Authorized laboratory	Annually
Preventive	Batteries replacemement	Authorized laboratory	At 300 charge cycles or after 24 months use
Ordinary	Cleaning of sensor lens	Operator	Each use
Ordinary	Visual inspection of the integrity of patient electrodes and sensor lens	Operator	Each use
Extraordinary	Disposing accessories and / or obsolete device in accordance with local regulations	Operator	When necessary

WARNINGS

Tampering with the device by the user and the failure of the maintenance table above involve the termination of the guarantee.

WARNINGS

In order to ensure the safety of the patient and / or operator the legislation provides instrumental tests of currents leakage and electrical safety.

10 ENABLE STAFF FOR THE USE OF THE DEVICE

The use of the device is only for authorized staff:

- MEDICAL / PARAMEDIC who has specific knowledge of the product and enabled by law.
- UNPROFESSIONAL STAFF (as the standard CEI EN 60601-1-11 point 3.3) that obtained authorization from SALUBER MD.
- Private user.

CAUTIONS

The Saluber MD declines all responsibility arising from the use of the device by unauthorized staff and from a misuse of the CorX.

11 PRECAUTIONS

Before making an examination, the operator must verify the absence of contraindications reported in section 12 of this manual.

WARNINGS

During operation of any operation, intervention and / or displacement not explicitly provided for in this manual can cause malfunctioning of the device establishing danger both for the subject treated and the operator.

WARNINGS

Before use of the device, visually inspect:

- Charging cables and integrity of device.

12 CONTRAINDICATIONS

- The CorX Smartwatch (Model: SMD1800) cannot be used by children under 18 years old.
- Do not use this device if you are pregnant or obese.

- The device is not intended to substitute for a hospital diagnostic ECG device, and also not to be used on patients with implanted cardiac devices, such as pacemakers and/or implanted cardio-defibrillators (IDCs).

WARNINGS

Do not apply the electrodes on:

- Cuts;
- Wounds;
- Solution of continuity of the skin.

13 ASSOCIATION WITH OTHER EQUIPMENT

It is not expected the simultaneous use of other equipment that are delivering electric fields or other forms of energy.

It is not recommended therefore concurrent use of the device with other devices, the fact that, given the unpredictability of the interference that may occur, could establish situations of risk to the patient subjected to an examination (unless otherwise prescribed).

14 HOW TO USE

Place the device stably and safely.
Read the entire manual carefully.
After considerable inactivity of the CorX (over 30 days), fully charge the batteries.

Before you can use the CorX you need to download and install on your Android device, iOS the control software CorX. This action should be performed once for the device from which you want to control the CorX, however APP CorX is continuously updated and enriched with new features, so it is advisable to always install the updates that are periodically released.

14.1 CorX SaluberMD app registration

To download the SaluberMD app for iPhone, connect to the Apple Store, for Android smartphone, connect to the Google Play Store and look for the SaluberMD app.

After downloading the app, you must register your device.

On the registration screen, enter your personal data and contact details.

Choose any username, and then in the code field enter your user code.

Your password must have at least 8 characters and must consist of at least one capital letter, a lowercase letter, a number and a special character (example: like@!?)

To finalize your registration, click the "Register" button, and access the app by clicking on the "Access" button on the home page.

Once you have removed the CorX from the box, charge the CorX for at least 4 hours.

After charging is complete, place the CorX in front of you with the word CorX at the bottom.

Switch it on by pressing on the button positioned on the lower right side of the device for 3 seconds.

At this point, you will see the initial setup screen, and will need to pair the device with the SaluberMD App and your phone.

(Note: Make a selection within 5 seconds, otherwise the screen will turn off to save power.)

To return to the main screen at any time or turn the CorX on again, just press the button on the lower right side.

14.2 Connecting the CorX with the SaluberMD app

Please check that the Bluetooth function on your phone is turned on and wear the CorX on your wrist. Open the app and enter your username or email and password to log in. Choose the “Wellness Service" section from the general menu.

Click on “Manage CorX” to scan and connect the watch with the app.

On the “Medical Device Data” screen, click on the blue "SCAN" button located in the center.
Wait for the app to search for the device and find the CorX. This will take about 30 seconds. For iOS, there is a message appears confirming successful pairing to your device, check the serial number to verify that it matches your unique CorX code.

In the app screen under the line “Select a device to connect”, select your CorX ID by clicking on the line with the name "CORX_ [your nr]”

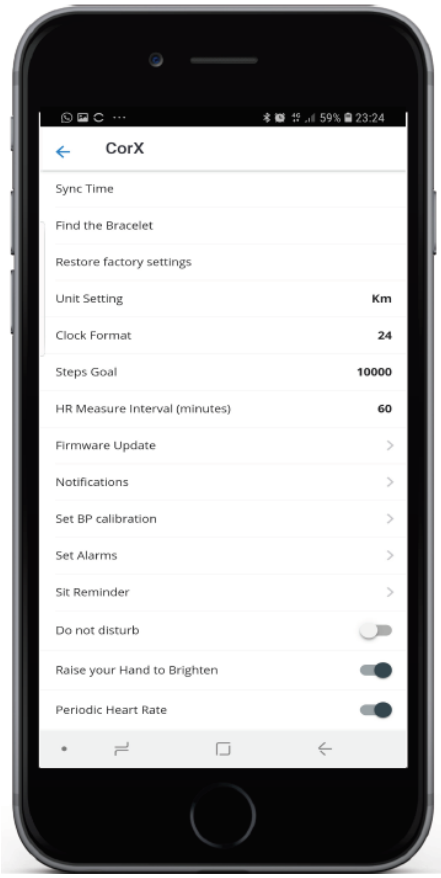
14.3 Setting up the CorX

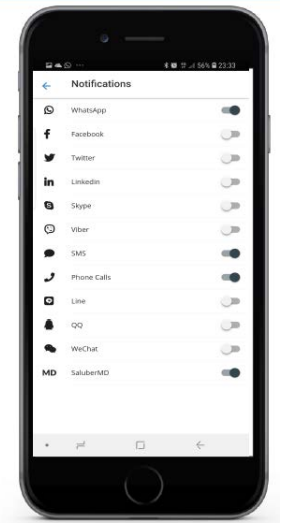
In this page the first step to execute is to check the Firmware Update so assure to setup the last version. In the case the app download the last version of the watch firmware and upload it on the watch.

Then it is possible to setup the user's preference as:
- Unit Setting,
- Clock Format,
- Step Goal,
- HR measure interval (minutes).

It is possible also Find the Bracelet and Restore the factoring settings.

It is possible to setup the Notifications, calibrate the Blood pression limits, Alarms, Sit Reminders, Do not Disturb, Raise your hand to brighten, Periodic Heart Rate, Disable Panic Button.

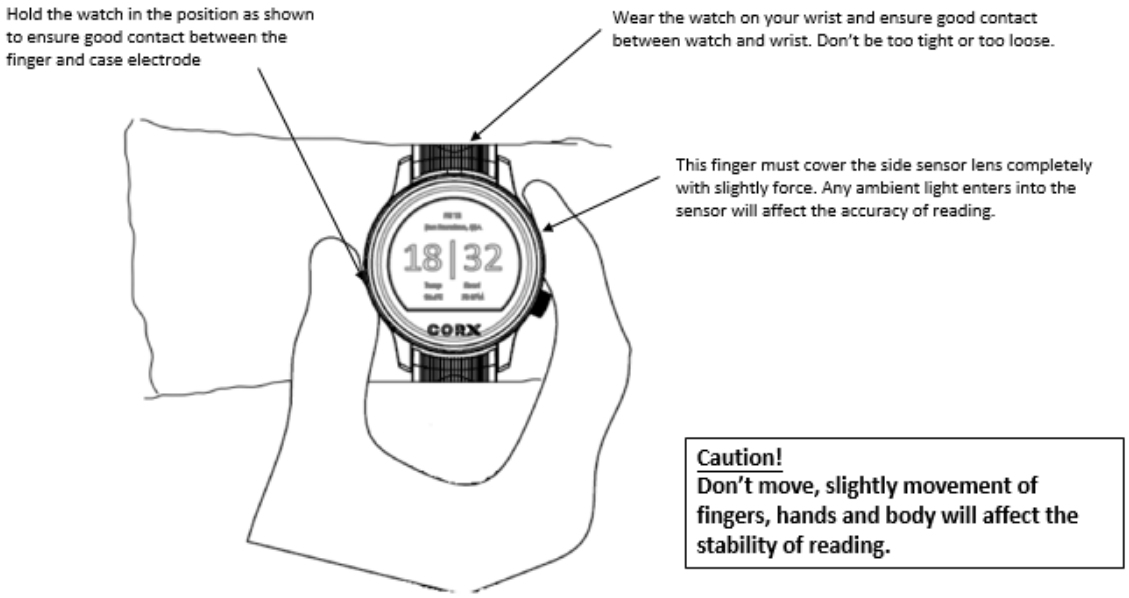




14.4 Taking your medical test

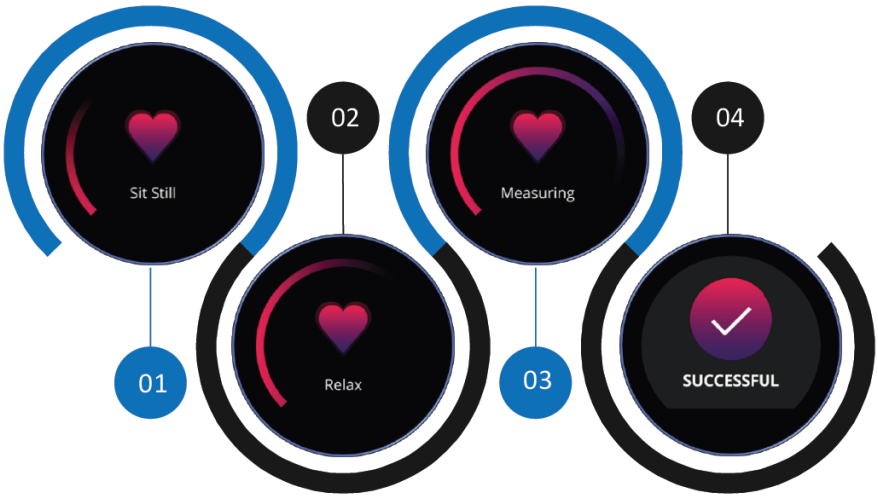
Choose a quiet place, sit comfortably with legs uncrossed and avoid speaking during the 45 seconds of medical data measurement. If possible, place your forearm on a table to keep the measurement steady. The sensors are positioned on the top right and bottom left of in addition to sensors on the back of the device, therefore, the CorX must be worn and not just resting on the wrist.

If necessary, apply slight, but not excessive, downward pressure on the CorX. With daily use you will learn how much pressure is required.



Correct positioning of the fingers

You will see a countdown on the screen, and then the measurement of medical data will start.



The screen will show “Successful” when the test is complete, and the 3 measured values, HR – Sp02 – Respiration, will appear briefly on the screen. You can see them by swiping from right to left.
If you require more time to see your results, push the “Medical Test” icon again, and swipe your finger across the screen from right to left until the “Test Result” icon appears. Push this, and swipe again from right to left.

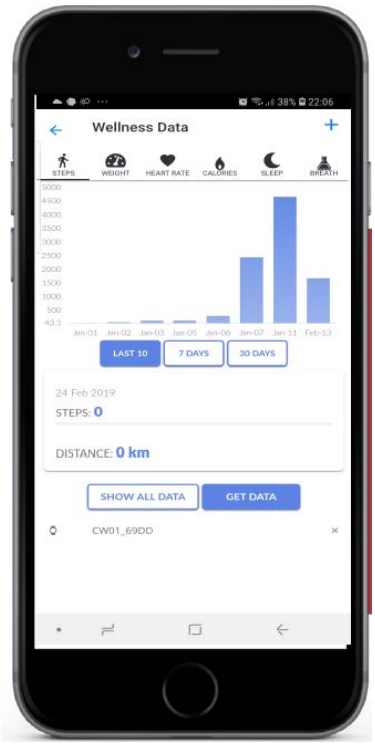
CAUTIONS

- Sit down calmly, keep still and do not move during 45 second medical test measurement. Slightly movement including fingers, hands and body will impact the stability of measurement result.
- The EKG electrodes must have good contact with both wrist skin and fingers for accurate EKG measurement.
- Correct placing of your finger on the device sensor is critical for accurate SpO2 measurements.
- Avoid applying excessive pressure to the sensor as this may case inaccurate SpO2 reading.
- If the test is unsuccessful, the test result will show “---“. You may check again by following section 15 TROUBLE SHOOTING.

14.5 How to get “Wellness data”

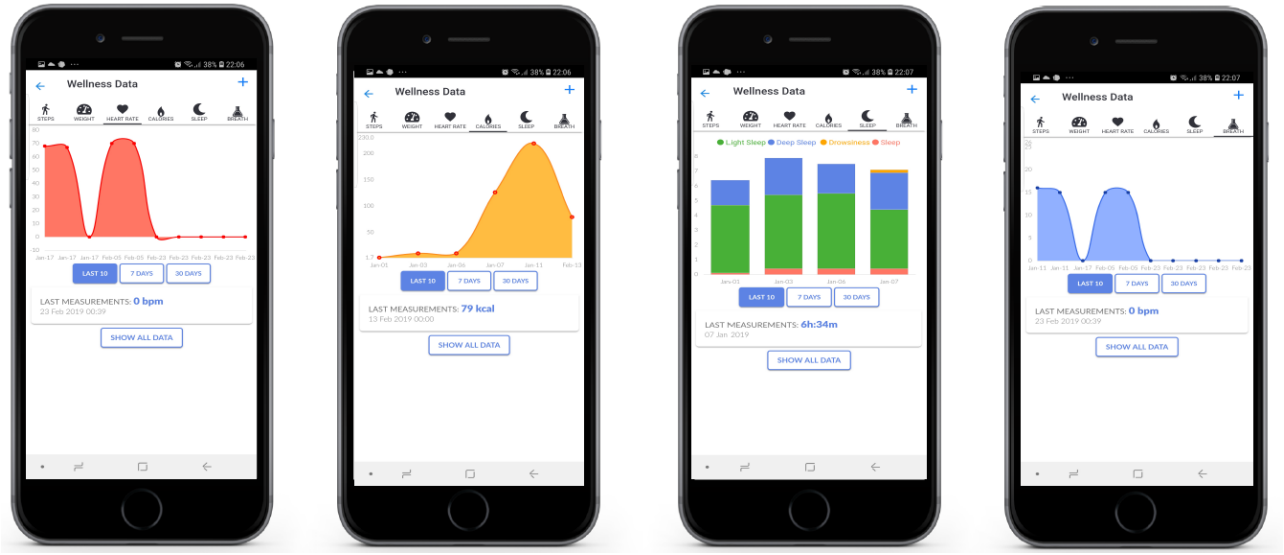
Go to the app’s main menu and click on "Wellness" > “Wellness data” and click on the blue "Get data" button.

You will have to do this only once, at the time of initial setup of your CorX. This allows the app to make the connection with your CorX Smartwatch.



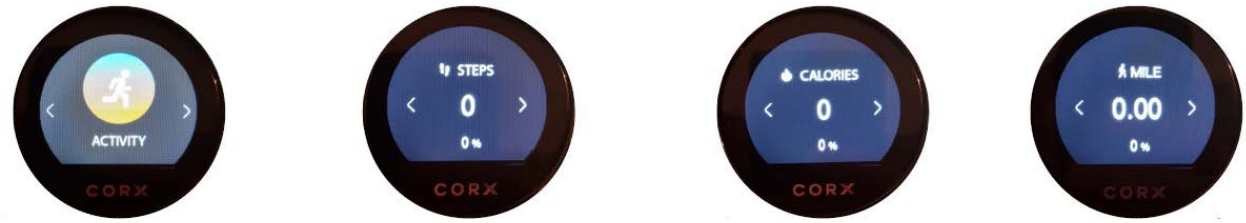
A green banner on the upper side will appear after the successful synchronization, but no data will be collected at this time.

Now you are able to collect your first Wellness data, and the SaluberMD app will connect to the CorX. Once the measurement has been downloaded, the data will be visible in the app.



14.6 Smartwatch functions

The other smartwatch functions are:
- Activity: where the user can control the number of daily steps, the burned Calories and the walked Miles



- Notifications: where the user can read the notification from the social apps (e.g. Whatsapp, Facebook, Twitter, LinkedIn, Skype, Viber, SMS, Calls, Line QQ; WeChat)

- Stopwatch: where the user can start the count just tapping on the screen

- Timer: where the user can set the countdown

- Change face: where the user can change the watch face

It is possible to use the smartwatch CorX as an Emergency phone. Tapping on the menu in the picture, if the phone is BT connected with the CorX, it will start a phone call at the phone number defined in the User profile.

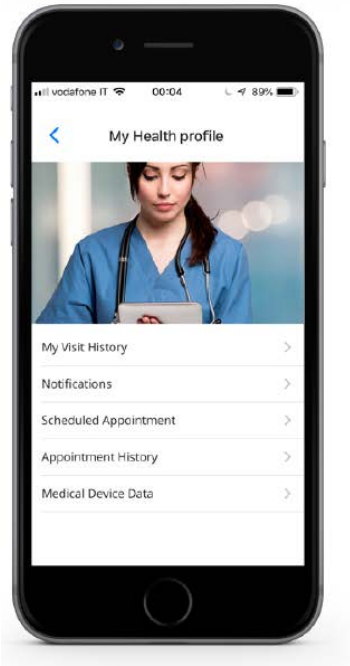
In the settings menu the user can see the ID number for the BT paring:

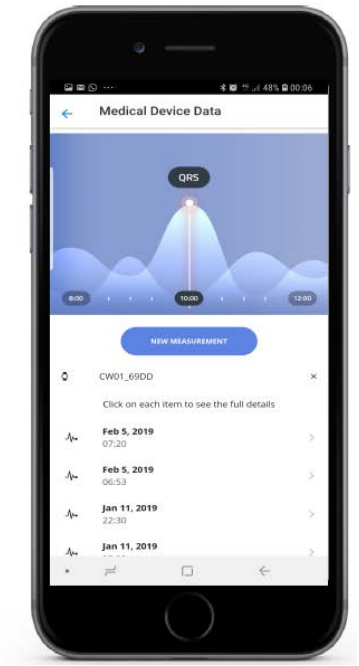
The user can Power off the CorX:

The user can Reset the CorX deleting all the stored data:

14.7 Using the SaluberMD app

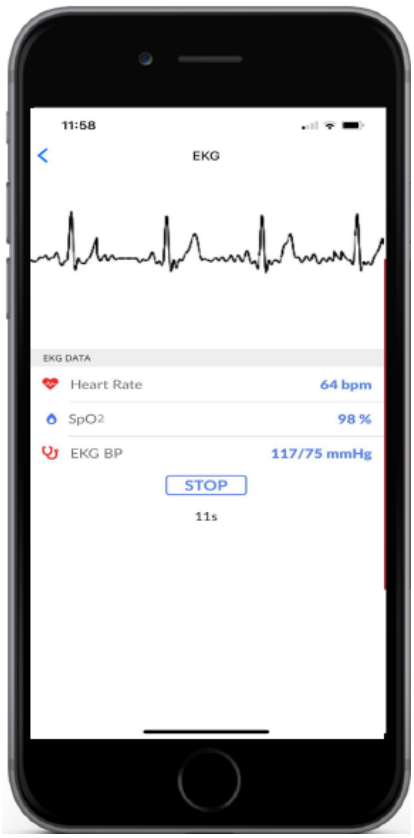
The SaluberMD app will connect to the CorX automatically. To take the measures the user selects My Health File / Medical Device DataMedical

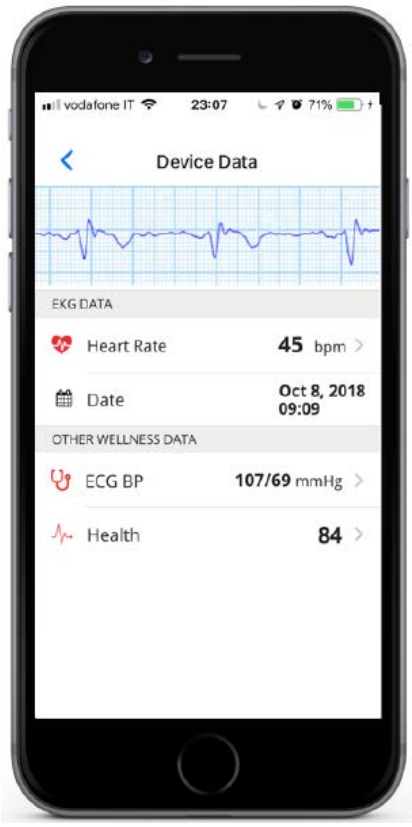




In this menu it possible execute all the tests with CorX:
- EKG
- SpO2

In the EKG menu it is possible to see the list of the past measurements.vice Data



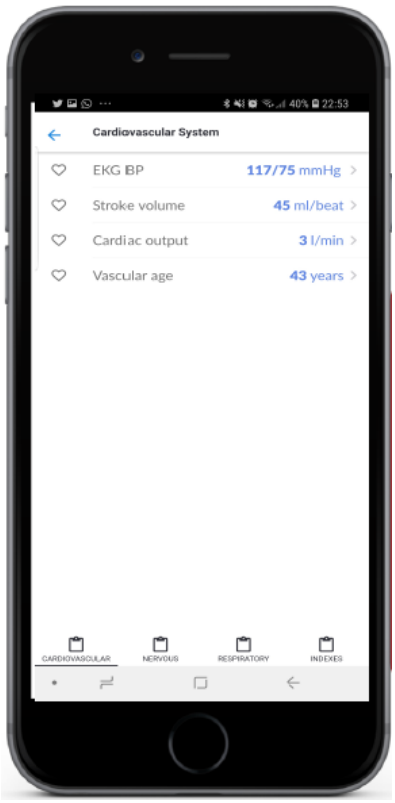


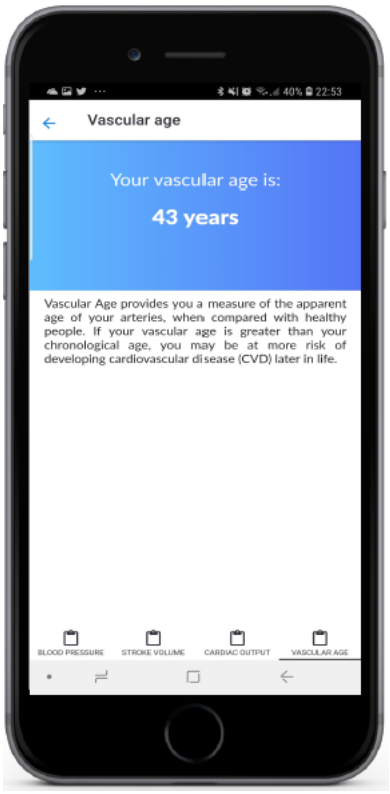
The SaluberMD app will connect to the CorX automatically and it is ready to execute the EKG. During the examination test the user can see the trace of the EKG.

Choose a quiet place, sit comfortably with legs uncrossed and avoid speaking during the 45 seconds of medical data measurement. If possible, place your forearm on a table to keep the measurement steady. The sensors are positioned on the top right and bottom left of in addition to sensors on the back of the device, therefore, the CorX must be worn and not just resting on the wrist.

If necessary, apply slight, but not excessive, downward pressure on the CorX. With daily use you will learn how much pressure is required.

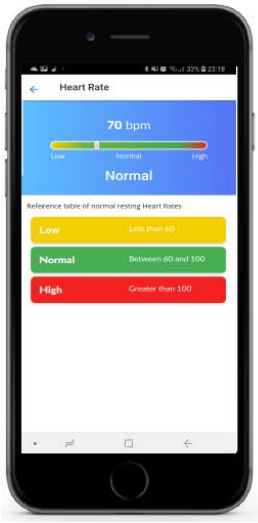
The user will see a countdown on the screen, and then the measurement of EKG will start. At the end of the test the user can download the EKG in pdf format file.



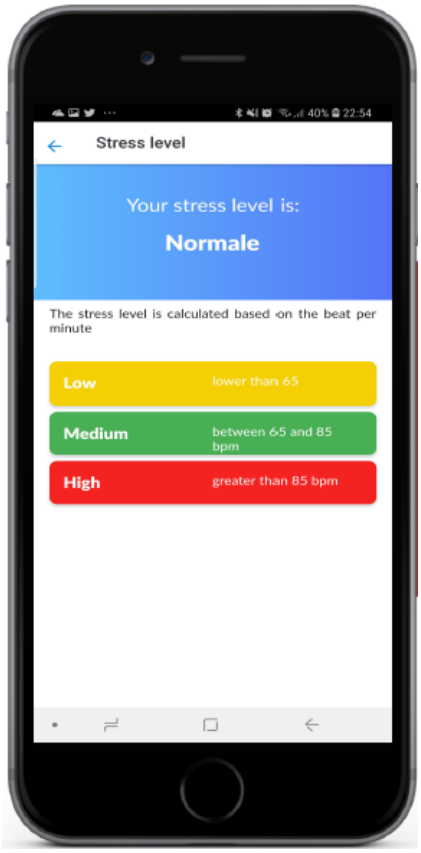


Once the measurement has been downloaded, the data will be visible in the app and recorded in the My Health Profile as the following indexes calculated by the SaluberMD algorithms.

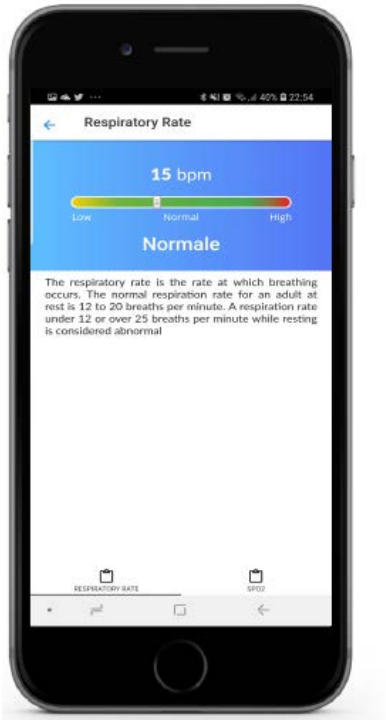
The user will be able to follow the complete path of the EKG, Heart rate, EKG-Blood Pressure (not a clinical reading), Stroke Volume, Cardiac output and date of this measurement by pushing on the date/hour line.



The app evaluate the data of the Stress Indexes of the user and other data as the Respiratory Rate and the SpO2.

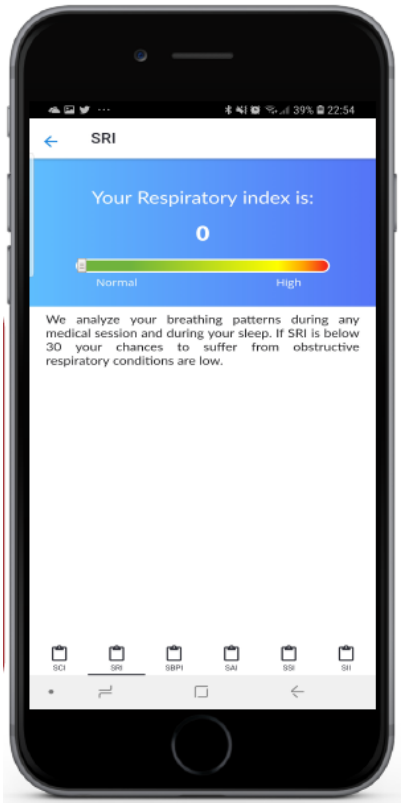


The user will be able to follow the complete path of the Pulmonary Indexes and date of this measurement by pushing on the date/hour line.



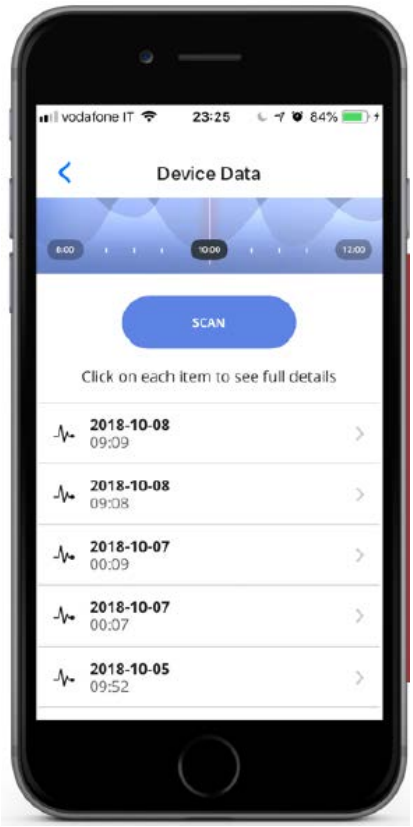
Once the measurement has been downloaded, the data will be visible in the app and recorded in the My Health

Profile as the following indexes calculated by the SaluberMD algorithms.

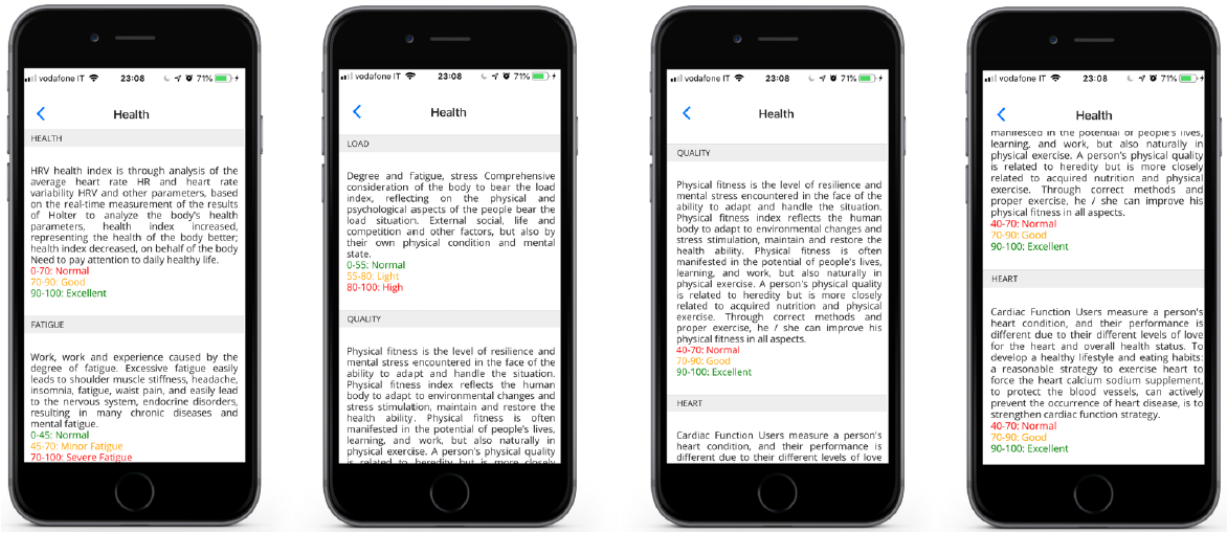


The user will be able to follow the indexes score as Cardiac and Respiratory Indexes, Blood Pressure Index, Activity Index, Stress Index, Insurance Index.

Your measurements will also be available within your "My Medical File" in the "Medical info"> EKG section. Each time you want a new EKG measurement, repeat the operation: from the main app menu, go to “My Health Profile” > “Medical Device Data” > “EKG” > and push the blue “Get Data” button.



You can view more information about your Health data by pressing the question mark next to the number (shown in the image above, on the screen at far right). The EKG list will be updated and saved in historical order after each measurement. The watch will display the most recent measurement at the top of the list.



Warining：

(1) This device may not cause harmful interference

(2) this device must accept any interference received, including interference that may cause undesired operation.

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

Note: 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.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

15 TROUBLE SHOOTING

CorX malfunctions

PROBLEM	***CAUSE***	***ACTION***
The system does not turn on	Low battery	Charge the battery
	Defective battery (ex: Not charging)	Check connections
	The charger does not work properly	Check connections
		Contact the dealer
	Software malfunction	Contact the dealer
System turns off immediately after turning on	Low battery	Charge the battery
	Hardware configuration error	Contact the dealer
The system does not turn off	Software malfunction	Contact the dealer
The system does not respond to the WiFi radio requests	Hardware problem (ex: the WiFi module is broken)	Contact the dealer
Incorrect data acquisition	Sensors not properly connected to the electrodes	Check sensors condition
	Electrodes not correctly positioned on the patient	Check electrodes condition
	Hardware problem (ex: sensors / cables damaged, softwaremalfunction)	Contact the dealer
Medical test unsuccessfully	1. Finger may not touch the SpO2 sensor lens in whole window zone area. 2. Finger may be moving during test. 3. Finger pressed too hard on the SpO2 sensor lens.	1. Remove finger and retouch the SpO2 sensor lens to cover the whole window zone area. 2. To keep perfectly still and test again. 3. Finger touch on the SpO2 sensor lens softly.
EKG waveform drifts or disappear	1. The rear electrodes from the watch bottom not touch the skin. 2. The thumb may not touch to the side electrode. 3. Hand or body may be moving. 4. Skin or hands are dry.	1. Tighten the strap to ensure the rear electrodes touch the skin. 2. Finger touch to side electrode correctly. 3. Try to keep still and test again. 4. Moisten the skin and hands using a damp cloth.
SpO2 or pulse rate shows no value or the number fluctuates	1. Finger may not be touching correctly. 2. Finger or hand may be moving	1. Remove finger and place gently on the lens. 2. Try to keep perfectly still and test again.
SpO2 value is too low or not show reading	1. Finger pressed too hard. 2. Finger may not be placed correctly. 3. Poor blood circulation.	1. Place your finger on the lens gently and stably. 2. Make sure your finger is in the right position and covers the lens completely. 3. Rub your finger to increase circulation, or test with another finger.
CorX cannot connect to the SaluberMD App for Android or Apple phone	1. The bluetooth symbol disappear on watch display. 2. The CorX is connected other device and not yet disconnected.	1. Go to SaluberMD app, go to manage CorX, scan device to get correct CorX ID and connect it. 2. Make sure you disconnect bluetooth with similar smartwatch and the app.

		If you are using Apple device, you should go to phone settings, check bluetooth connection need to un-pair or disconnect device, press forget device. Then go to SaluberMD app, go to manage CorX, scan device to get correct CorX ID and connect it.
Cannot be powered up	Low battery	Charge the watch (around 2.5 hours to fully charge)
	The button didn't pressed for long enough	Press and hold the push button (crown) until the watch power up (normally 3 seconds)
	The watch didn't turn on for too long and in deep sleep mode	Wake up the watch by connect the cable with power
White screen on the App	Server down / No Internet access	Make sure there is Internet access, if yes, try to quit the app and re-run the app (to quit the app, double click the home button for <=iPhone 8 or swipe up from low edge and hold the finger on the screen for iPhone X, then swipe away the Saluber MD app)
The App crash or hang up	App not stable / Server down / No Internet access	Make sure there is Internet access, if yes, try to quit the app and try again. If still not fixed, try to remove the app from iPhone completely (by press and hold the app icon from home screen and click the "x" at upper left corner at the app icon) and reinstall the app from app store to see if it fix (need to input the user name and password after reinstall).

Control software malfunctions

PROBLEM	***CAUSE***	***ACTION***
The software does not connect with the CorX	Hardware problem (ex: the WiFi module is broken)	Contact the dealer
	The communication between the two devices is disturbed	Approach the 2 devices
Incorrect data acquisition	Malfunction of your device (smartphone, tablet, PC, Mac)	Restart your device
The application is blocked	Software malfunction	Turn off your device. If the problem reoccurs, contact your dealer.

16 ADDITIONAL INFORMATIONS

Disposing of the device or part of it

NOTE

As required by Directive 96/2002 is required to not disposing the devices and / or parts of it, including consumable materials, such as household waste.
It must be carried out separate collection of all assemblies.

The manufacturer declares its availability to provide for free disposal, information on this can be obtained directly from:

- via e-mail
- via phone at the number
- via fax at the number

The manufacturer, in order to decrease the amount of waste generated will, where possible, to reuse and / or recycling of the system or part of it.

WARNINGS

Possible negative effects on the environment and / or health if not disposed of in conformity with the procedures.

The symbols below indicate the prohibition of uncontrolled disposal.

17 RESPONSIBILITY

The Manufacturer shall not be responsible for the safety, reliability and performance of the device if:

The device is not used according to the instructions in this manual.

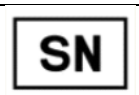
The electrical system where the machine (using the charge) is used does not comply with safety standards.

Repairs and periodic inspections are not carried out by the manufacturer or by an approved laboratory.

The Manufacturer declines any liability for damage caused to persons or property resulting from violation of the device or inadequate maintenance and failure to observe the provisions contained in this manual.

18 LABELING

These symbols may appear on the device or packaging labels.

Symbol	Meaning
	Serial number
	Manufacturer
	Manufacture date (production year)
	CE marking: In conformity with Directive 93/42/EEC for Medical Device
	Indicates separate collection for electrical and electronic equipment (WEEE)
	Authorized representative in the European Community
	FCC mark: Indicates that the electromagnetic interference from the device is under the limits approved by the FCC
	Consult instructions for use
	Type BF Applied Part (Class of electrical safety)
IP67	Protected from total dust ingress and from immersion between 15 centimeters and 1 meter in depth

19 SHEET MACHINE

ITEM	MOTIVE ASSISTANCE	DESCRIPTION OF INTERVENTION	DATE	SIGN

20 DISCLAIMERS

Warning: Changes or modifications to this unit 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:

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

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.

21 TRADEMARK AND COPYRIGHT INFORMATION

SaluberMD LLC (Hereinafter called SaluberMD) owns the intellectual property rights to this CorX product and this manual. This manual may refer to information protected by copyrights or patents and does not convey any license under the patent rights of SaluberMD, nor the rights of others, intends to maintain the contents of this manual as confidential information. Disclosure of the information in this manual in any manner whatsoever without the written permission of SaluberMD is strictly forbidden.

Contents of this manual are subject to changes without prior notice. All information contained in this manual is believed to be correct. SaluberMD shall not be liable for errors contained herein nor forincidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Form no.： XXXXXX Version: 3.0, Date: Apr 2019

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