Conox® View Android
User Guide

Conox® View Android version 1.0

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1. APP PREREQUISITES

The application Conox® View Android was designed to run on Android devices with the following minimum requirements.

- ☐ Operating System
  - Android 5.0 or higher (API 21)
- ☐ Connectivity
  - Bluetooth
- ☐ Screen
  - 3.7 inches or higher
- ☐ Memory
  - ROM: 1 GB or higher
  - RAM: 1 GB or higher
  - Externals: SD
- ☐ Processor
  - 1.2 GHz or higher

Quantium Medical does not guarantee that the application runs on all Android devices that meet the requirements because in the market there is wide range of devices and it has not been possible to test all.

2. CYBERSECURITY CONSIDERATIONS

The figure below provides an overview of intended use conditions related to the ConoxView application.

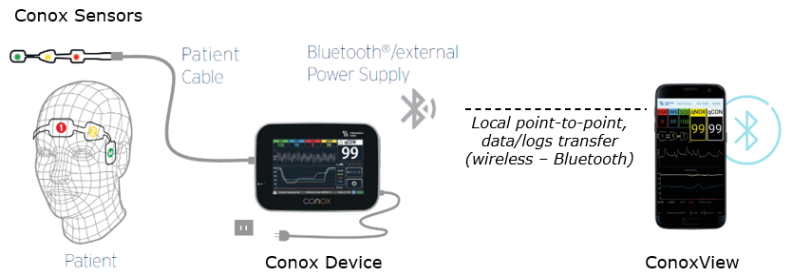


Figure 1 – ConoxView diagram

Ensure the application is installed on a trusted device (not rooted) and used by authenticated local users.

Ensure the hosting operating system environment provides up-to-date malware protection (anti-virus) solution.

Ensure ConoxView data are managed as recommended in Section 7 "FILES

STORED~~FILES STORED~~" of the present user manual. Once Conox data are transferred on the host operating system, end-users are responsible to ensure Conox data are protected from unauthorized access and tampering attempts which could lead to confidentiality or integrity compromise of those data.

Check regularly for latest updates of the application from Mobile Application Store (Google Playstore here for Android).

If you suspect a cybersecurity attack occurred or a vulnerability related to the ConoxView application, please report this to your local Fresenius Kabi representative or submit a request to the Fresenius Computer Emergency Response Team (CERT - cert@fresenius.com).

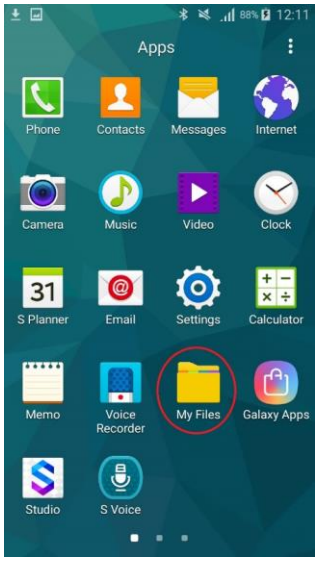
~~2.~~3. INSTALLATION

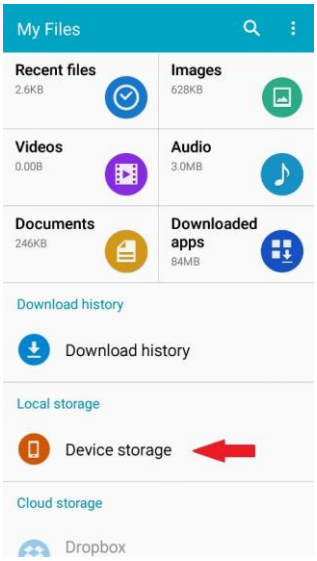
The installation of the Conox® View Android application can be made by copying the "Conox_View_Android.apk" installer file on an Android device or by downloading the Conox® View Android app from the Google Play Store.

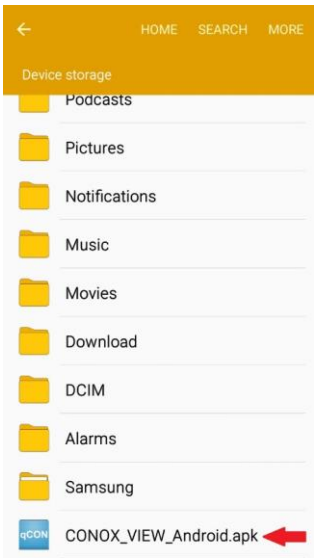
In the case the user has to install the application with the installer file, the next steps should be followed; note that these are general steps because there could be differences between some Android devices:

1. Copy the application installer on Android device internal memory; this is done connecting the Android device to a PC with the USB cable that is provided with the Android device (for more information look at the Android device user manual).

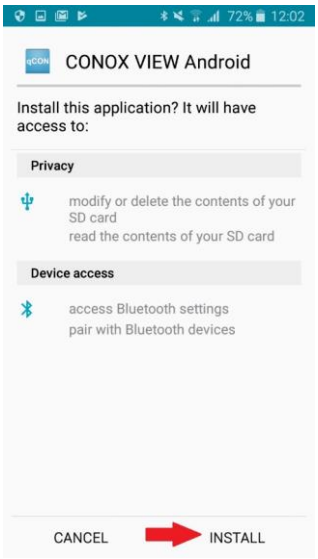
2. Disconnect the Android device from the PC, then in the Android device look for the application installer in the internal memory; this is done with any file explorer application that has the Android device, if it is not installed on the device it is possible to find it in the Internet or Google play store, for more information see the Android device user manual.



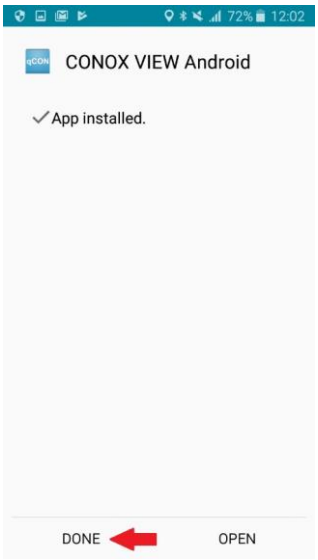




3. Touch the application installer to start the installation wizard, touch on "Install" button to begin the installation (some Android devices have unselected the security option of "Unknown sources", if this is the case, the installation wizard will show a message from where it is possible to select the option, then repeat the previous step and touch the application installer).



4. Wait until the application installation ends, then touch on "Done" button and exit from the file explorer.



5. Go to applications and widgets menu, and then verify that the application is installed with looking for the Conox® View Android icon.

6. Activate the Bluetooth of the Android device and ensure that the Bluetooth of the Conox® monitor is enabled.
7. Pair the Android device with the Conox® monitor by using the Bluetooth settings of the Android device.
8. When the Conox® View Android application is started, a list of the Conox® monitors that are paired with the Android device is displayed.
9. Tap on the desired Conox® monitor in order to start the recording. The Conox® monitors can be identified by their serial number.

3. APP CHARACTERISTICS

The characteristics of the application can be divided into the next blocks.

- ☐ **Action Bar**
  - Set the EEG signal amplitude: ±25μV, ±50μV, ±120μV,±250μV y ±475μV.
  - Set the EEG signal time scale: 3 s, 6 s and 9 s.
  - Set the trend time scale: 5 minutes, 30 minutes and 60 minutes.
  - Select Conox before starting the recording (this button is not enabled during the recording).
  - Previous Case: show the index trends and events of a previous registered case
  - The about message button.

- ☐ **Indexes Parameters**
  - Index of consciousness (qCON).
  - Index of nociception (qNOX)
  - Electromyography (EMG).
  - Burst Suppression Rate (BSR).
  - Signal quality index (SQI).
  - Impedance value on each electrode.

- ☐ **Graphs**
  - EEG signal.
  - Pinch open and close for EEG graph to zoom in and out over the Y axis.
  - Index trends qCON, qNOX, EMG and BSR.
  - Tap on the index legends in order to show or hide the respective trend.

- ☐ **Annotation box**
  - An annotation box to write events and comments that are stored in the log file.

- ☐ **Status Bar**
  - Status of what the app is doing.
  - Storing file indicator.
  - Tap on the storing file indicator value in order to enable or disable the file storing.
  - Elapsed time indicator.

- ☐ **Messages**
  - Pop-up messages that indicates an event detected by the Conox® monitor (impedance measuring, artefact or lead off).
  - Pop-up message of loss of connection with the Conox® monitor.
  - Exit message with YES and NO buttons to confirm stay or quit the app.
  - Stop/Start saving file message with YES and NO buttons to confirm the change of the option of saving file.

- **Changing Android device orientation**
  - The application changes its user interface when the user changes the orientation of the Android device.

- **Reconnection**
  - The application is able to reconnect in the case of the Conox® monitor is reconnected.

- **Stores files**
  - The application stores a binary file with all the data sent by the Conox® monitor and a text file with the indicator parameters and annotations made by the user.

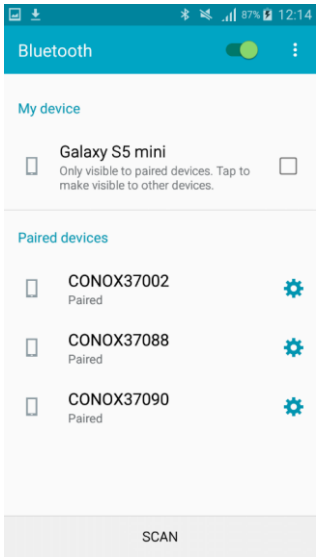
- **Languages**
  - English.
  - German.
  - Spanish.

4 GENERAL OPERATION

The application works by receiving data from the Conox® monitor through Bluetooth. The application is able to manage the Bluetooth connection (detection and reconnection) with the Conox® monitor. All data are processed (indexes and EEG) in the Conox® monitor and application only reads and displays the data without modification.

4.1 RUNNING THE APP

Before running the Conox® View Android application, ensure that the Conox® monitor is paired with the Android Device.

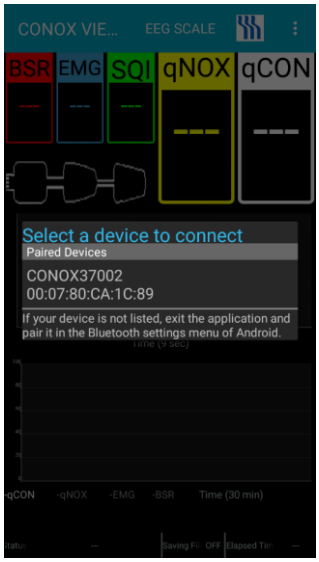


Select the Conox® View Android icon from the set of applications of the Android device or from a shortcut on some of the desktops available in the Android operating system.

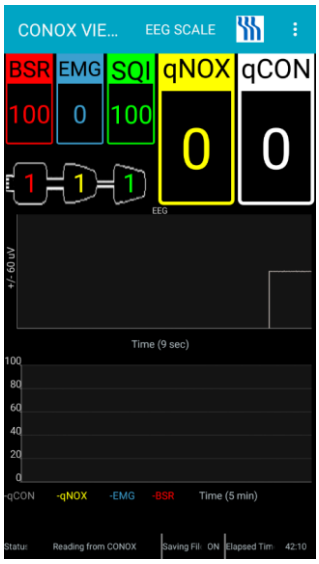
The way to put a shortcut to any of the Android desktops varies in function of Android versions, it is recommended to see the user manual or support information of Android device to put the shortcut.

When the Conox® View Android Application starts, a list of the Conox® monitor that are

paired with the Android Device is displayed.

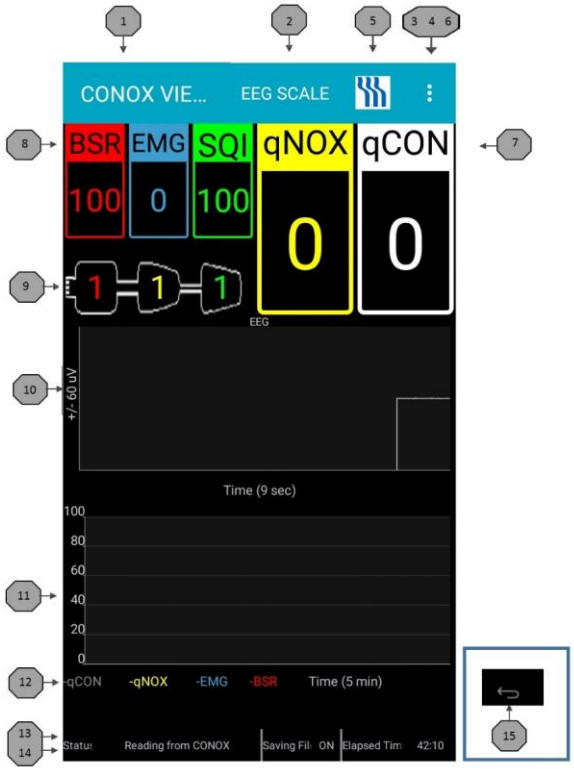


To select the desired Conox® monitor tap on its name and serial number. The recording will start.



4.2 USER INTERFACE DESCRIPTION

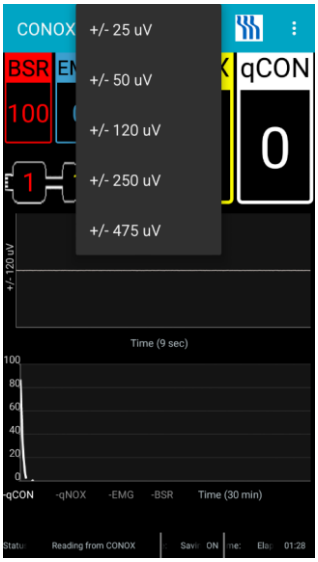
4.2.1 Initial interface



1. Conox® View Android Title.
2. EEG scale selector button.
3. EEG time scale selector button.
4. Index Trend Time Scale selector
5. Logo.
6. Select Conox®, Previous Case and About button.
7. qCON and qNOX Indexes.
8. BSR, EMG SQI Indexes.
9. Impedances.
10. EEG graph.
11. Indexes graph.
12. Indexes Legend/Show and Hide Index from graph.
13. Annotation box.
14. Status bar.
15. Back button to exit from the application.

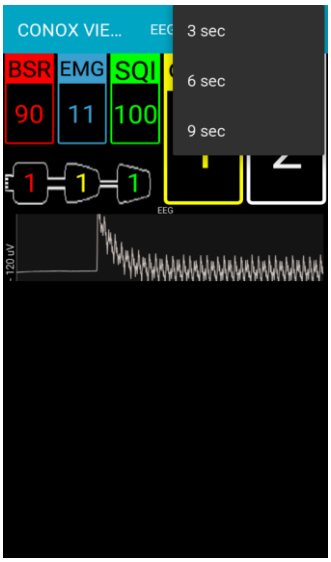
4.2.2 Changing the EEG signal scale

The default scale value is ±120μV. To show the available scales press the "EEG SCALE" button in the action bar of the application. Then press the chosen scale to change the Y axis scale of EEG signal.



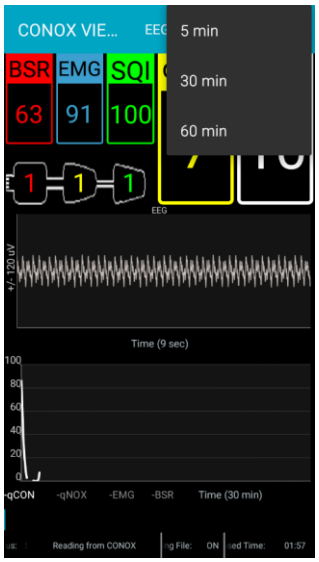
4.2.3 Changing the EEG signal time scale

The default time scale value is 9 s. To show the available scales press the "EEG TIME" button in the action bar of the application. Then press the chosen scale to change the X axis scale of EEG signal.



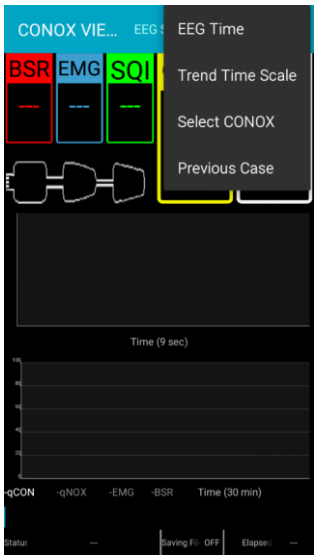
4.2.4 Changing the index trend time signal time scale

The default time scale value is 30 minutes. To show the available scales press the "TREND TIME SCALE" button in the action bar of the application. Then press the chosen scale to change the X axis scale of index trend graph.

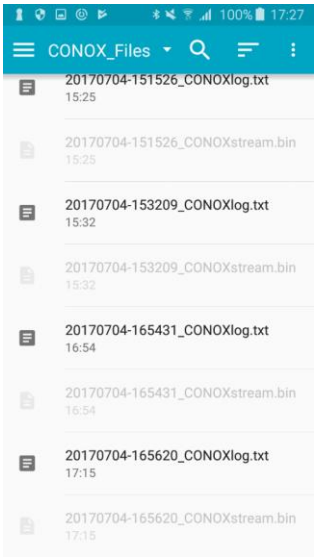


4.2.5 Previous Case

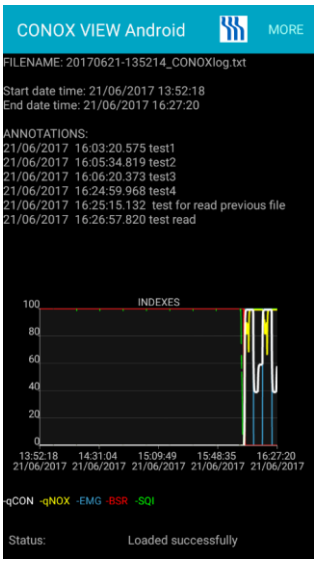
This button permits to open a previous registered case.



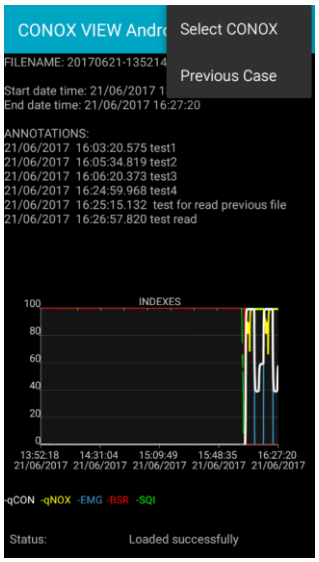
When this button is pressed, it is possible to browse all the case file that are stored in the Android device. In order to browse the previous case, a file manager installed on the Android device is required. There are many free app in the Google Play Store that permits to manage the files. For example "ES File Explorer" can be a suitable file manager option. The layout and the way to find the Conox® previous file may change depending on the specific file manager. In case the Conox_File folder is not directly opened when the Previous Case button is tapped in, please search for the file manager icon and look for the Conox_Files folder on the Device Storage.



Tap on the desired case in order to see the index trends and the annotation.



In order to display more case, tap again on the Previous Case button, otherwise tap on the action bar Select Conox button in order to start a new recording.



This button is not enable during the recording. In order to display a previous case, the recording must be stopped by using the back button of the Android Device and then restarting the Conox® View Android.

4.2.6 The about button

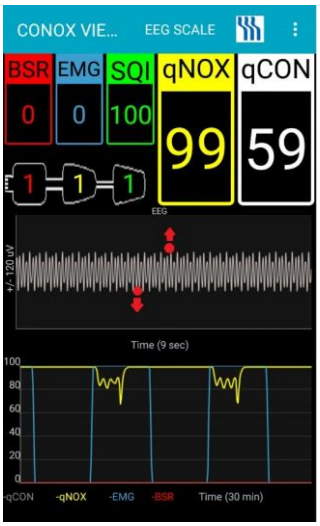
This button, when it is pressed, it shows the software version of the Conox® View Android, the firmware version and serial version of the Conox® monitor.

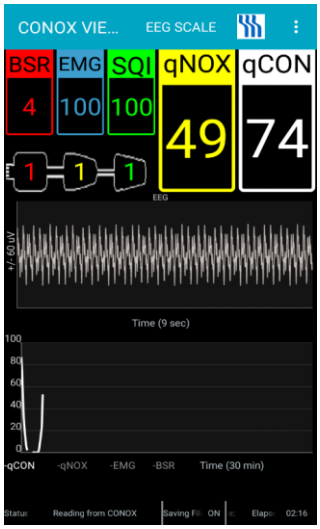
4.2.7 Select Conox button

This button displays the list of the Conox® monitor that are paired with the Android device in order to select a Conox® monitor to connect with and start the recording. This can be used before starting the recording, if the selected Conox® monitor is disconnected when the application is starting or if the user has closed the list of paired Conox® monitor. Once the recording is started and the Conox® View has started to receive data from a Conox® monitor, this button is disabled. In order to switch to another Conox® device when the recording has started, stop the recording by using the back button and restart the Conox® View Android.

4.2.8 The EEG graph

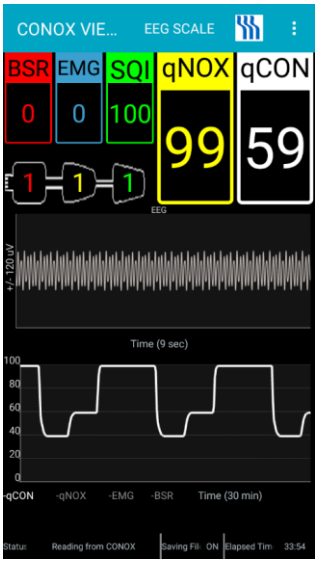
Besides changing the Y and X axis scale with the respective buttons, it is possible to change the scale of the Y axis of the EEG graph also with Pinch Open / Close.

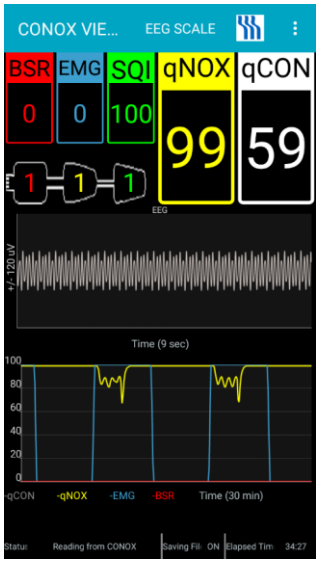




4.2.9 The Indexes graph

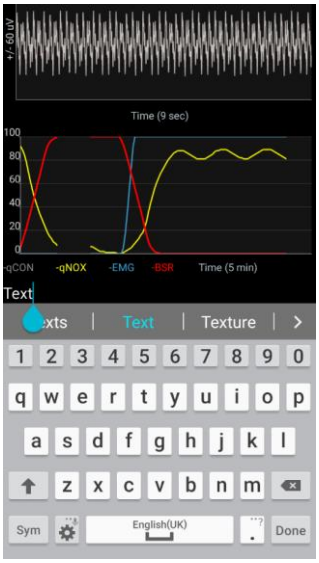
This graph shows the trends for the indexes (qCON, qNOX, EMG and BSR). You can show or hide an index on the graph by tap on the respective index legend. When the index is displayed on the graph, the color of the index legend name is the respective color of the index, while when an index is not displayed on the graph, the color of the index legend name is grey.





4.2.10 The annotation box

To make annotations in the log file, press the annotation box in the UI. After press the annotation, the soft keyboard is shown in the screen. The annotation is saved in the log file when the button "Done" is pressed.



4.2.11 The status bar

The status bar shows what the application is doing (connecting, reading and reconnecting); and also shows messages from Conox® monitor (Lead off, Impedance check and artefact). Then, it shows if the application is storing the files; and the elapsed time since the Conox® monitor is connected. In order to stop or start saving files, tap on the Saving File value, and a pop up message will ask for confirmation.


CONOX VIE...
EEG SCALE
BSR
EMG
SQI
qNOX
qCON
0
100
100
83
99
Do you want to stop saving CONOX files?
NO
YES
Time (5 min)
Reading from CONOX

4.2.12 The exit button

The correct way to exit the application is to use the back button that the Android device provides; these may vary according to each device. When pressing the back button a message asks confirmation about to exit or not.

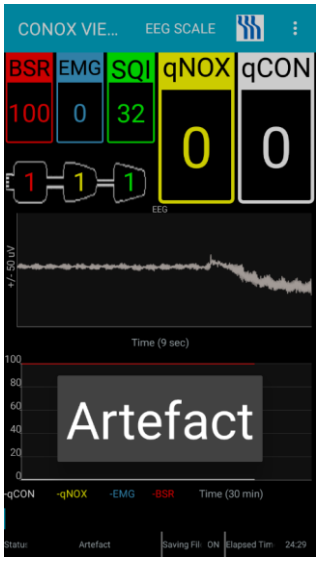
5 MESSAGES

5.1 MESSAGE "NO DATA RECEIVED FROM Conox"

The message No data received from Conox is shown in the event of not receiving any data from the Conox® monitor. An audible alarm sounds at the time of the message. After 7 seconds the application tries to reconnect and if no data are received, the alarm sound continues.

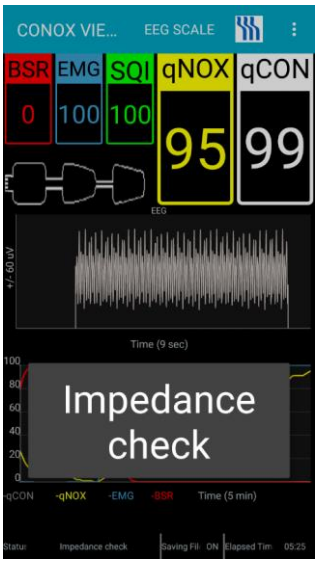
5.2 ARTEFACT DETECTION MESSAGE

The artefact message is displayed when the Conox® monitor detects artefact until the Conox® monitor has no detected artefacts. This event is logged every second in the Conoxlog file.



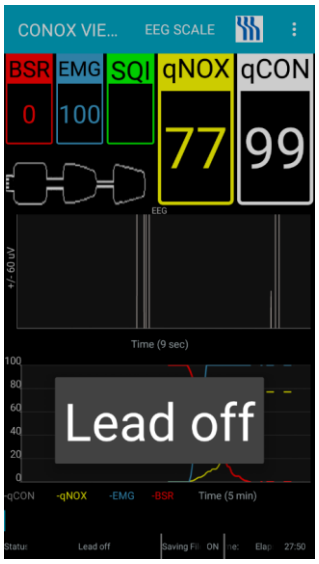
5.3 IMPEDANCE MEASURE MESSAGE

The impedance check message is displayed during impedance measurement that is made by Conox® monitor, this event is logged every second in the Conoxlog file.



5.4 LEAD OFF MESSAGE

The Lead Off message is displayed in the screen while the Conox® monitor no detects signal in anyone of electrodes of the patient cable or if the patient cable is disconnected. This event is logged every second in the Conoxlog file.

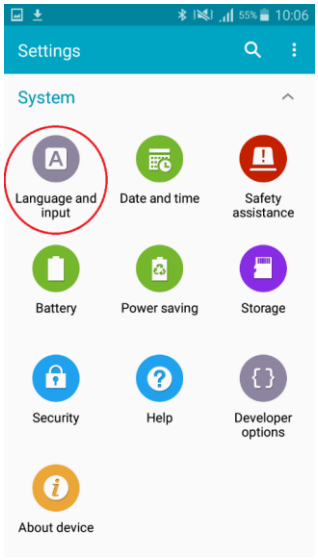


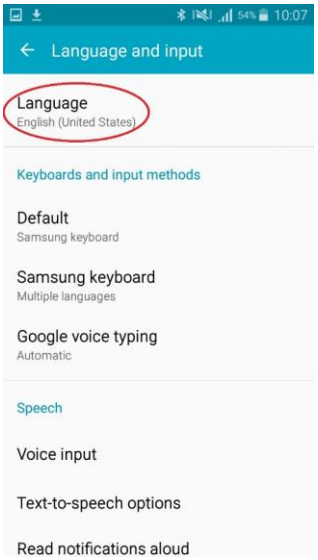
6 CHANGE LANGUAGES

This version of the application can change between the next languages:

- ☐ English (Default).
- ☐ German.
- ☐ Spanish.

To change the languages go to Android device settings by selecting its icon from the set of applications of the Android device. Then press the option "Language & input" to see the languages settings.





Then select "Language" to see the list of languages available in this Android device; and then look and select for any of the languages that supports the application.

English (New Zealand)

7 FILES STORED

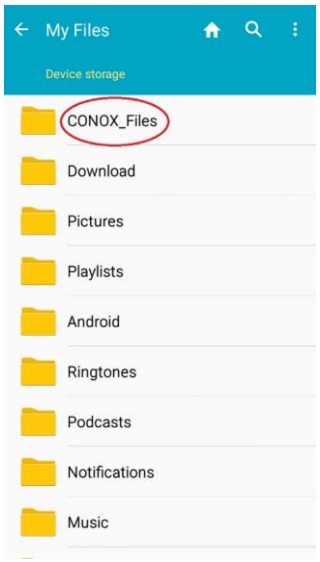
Two files are saved automatically every time the Conox® View Android is connected to the Conox® monitor. The format of each file is as follows:

Date-Time_Conoxlog.txt Date-Time_ConoxStream.bin

Ensure to have more than 100 MB free in the memory of the Android Device in order to save correctly all the data that are received.

7.1 LOCATION OF FILES STORED ON THE ANDROID DEVICE

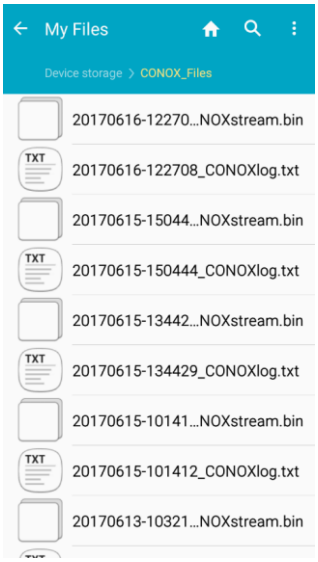
The files are automatically saved in Android device's internal storage, which is usually a SD memory. By default the application saves these files in the folder "Conox_Files", which is created by the application.



The way to view the files stored on the Android device is done via a file browser, it is possible to install the desired file browser from the "Play Store" of Android. Currently the most widely used are "ES File Explorer" and "ASTRO File Manager" among others.

The details of installing and using a file browser are out of scope of this document.

The next picture shows an example of some records made.


My Files
Device storage > CONOX_Files
20170616-12270...NOXstream.bin
20170616-122708_CONOXlog.txt
20170615-15044...NOXstream.bin
20170615-150444_CONOXlog.txt
20170615-13442...NOXstream.bin
20170615-134429_CONOXlog.txt
20170615-10141...NOXstream.bin
20170615-101412_CONOXlog.txt
20170613-10321...NOXstream.bin


-qCON
-qNOX
-EMG
-BSR
Time (30 min)
Spectrogram

7.2 COPY FILES STORED IN THE ANDROID DEVICE TO A PC

From a PC it is possible to download the files that are stored by the application. The connection details of Android device to a PC are in the user manual of the Android device.

On a PC with Windows 10 can take the following steps.

1. Connect the Android device to the PC; the PC will recognize it as a USB memory drive.
2. With Windows Explorer, navigate to the Android device's internal storage.
3. Find the folder "Conox_Files" and enter.
4. Inside the folder "Conox_Files" there are the records made, which can be copied to the PC.

8 SPECTROGRAM

Conox View computes shows the spectral density array in an image on the user interface. The spectrogram is available in the 3 time scales: 30, 60 and 5 min depending on the trend time scale user selection.

The spectrogram is a colored image which represents in the y axis the frequency f in the range $0<f<45$ Hz and in the x axis the last 30 , 60 or 5 minutes of recording

User can choose to show only spectrogram or index trends and spectrogram by the "Spectrogram" button on the user interface that allows the user to enable or disable the spectrogram image. By using this button and the "qCON", "qNOX", "EMG", and "BSR" legend button it is possible to switch between different views that show:

- only the index trend graph: default option or after tapping on "Spectrogram" button when enable.
- only the spectrogram: after tapping on "Spectrogram" button when disable or after disabling all the index trend graphs, when "Spectrogram" is enabled
- both the index trend graph and spectrogram: after tapping on one of the index trend buttons when "Spectrogram" is enable

The spectrogram image colors are proportional to EEG FFT Power. Color map unit is in dB (μV): 0 dB means a FFT power of 1 μV^2 which is equivalent to a sinusoid with amplitude $\sqrt{2}$ μV (Table 1).

Table 1. Association between the sinusoid amplitude in μV, the respective FFT power in μV^2

and dB and the color shown by the ConoxView

Sine Amplitude (μV) peak to 0	FFT Power (μV^2)	FFT Power (dB)	Color
$320*\sqrt{2}$	102400	50	
$3.24*\sqrt{2}$	10.49	10	
$1*\sqrt{2}$	1	0	
$0.32*\sqrt{2}$	0.1024	-10	
$0.10*\sqrt{2}$	0.01	-20	
$0.031*\sqrt{2}$	0.00096	-30	

Spectrogram is loaded in previous case tab. When the ".txt" of a previous case recorded loaded in the "Previous Case" view, the spectrogram is also shown.

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Field Code Changed

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