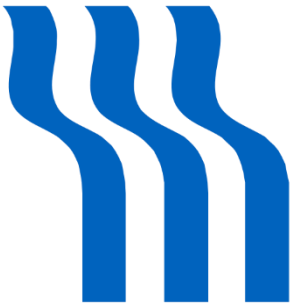
Conox View iOS
User Guide



FRESENIUS KABI

Conox View iOS

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TABLE OF CONTENTS

1. APP PREREQUISITES

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

- Operating System
  - iOS 13.0 or higher
- Connectivity
  - Bluetooth
- Screen
  - 3.7 inches or higher
- Memory
  - ROM: 1 GB or higher
  - RAM: 1 GB or higher
- Processor
  - 1.2 GHz or higher

Quantium Medical does not guarantee that the application runs on all iOS devices that meet the requirements.

2. CYBERSECURITY CONSIDERATIONS

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

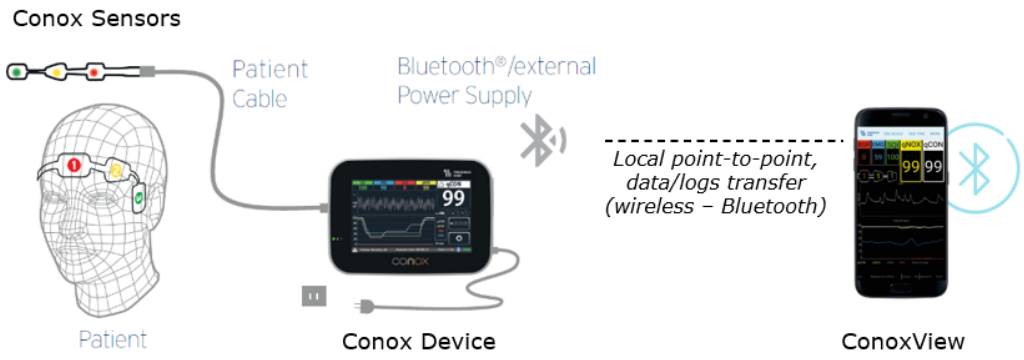


Figure 1 – ConoxView diagram

Ensure that the application is installed on a trusted device and used by authenticated local users.

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

Ensure that the ConoxView data are managed as recommended in Section "**Error! Reference source not found.**AGE" 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 the App Store.

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).

3. INSTALLATION

The app can be downloaded from the "Apple store". Please refers to the common Apple application downloading and installation process.

4. APP CHARACTERISTICS

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

- **Action Bar**
  - Set the EEG signal amplitude: ±25μV, ±50μV, ±120μV and ±475μV.
  - Set the EEG signal time scale: 2s, 4s and 8s.
  - Set the trend time scale: 30 minutes, 2 hours or 6 hours
  - 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 'Device Info' 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 indicate an event detected by the Conox monitor (impedance measuring, artefact or lead off).
  - Pop-up message of loss of connection with the Conox monitor.

- **File storage**
  - 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.

5. GENERAL OPERATION

The application works by receiving data from the Conox monitor through Bluetooth. The application is able to manage the Bluetooth connection 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.

The app is compatible only with Conox 2D (Firmware version 5.10 or above). Previous Conox versions are not supported.

5.1. RUNNING THE APP

Before running the ConoxView iOS application, ensure that the Conox monitor Bluetooth is turned on and that no other Bluetooth devices are connected and are transmitting data to the iPhone device.

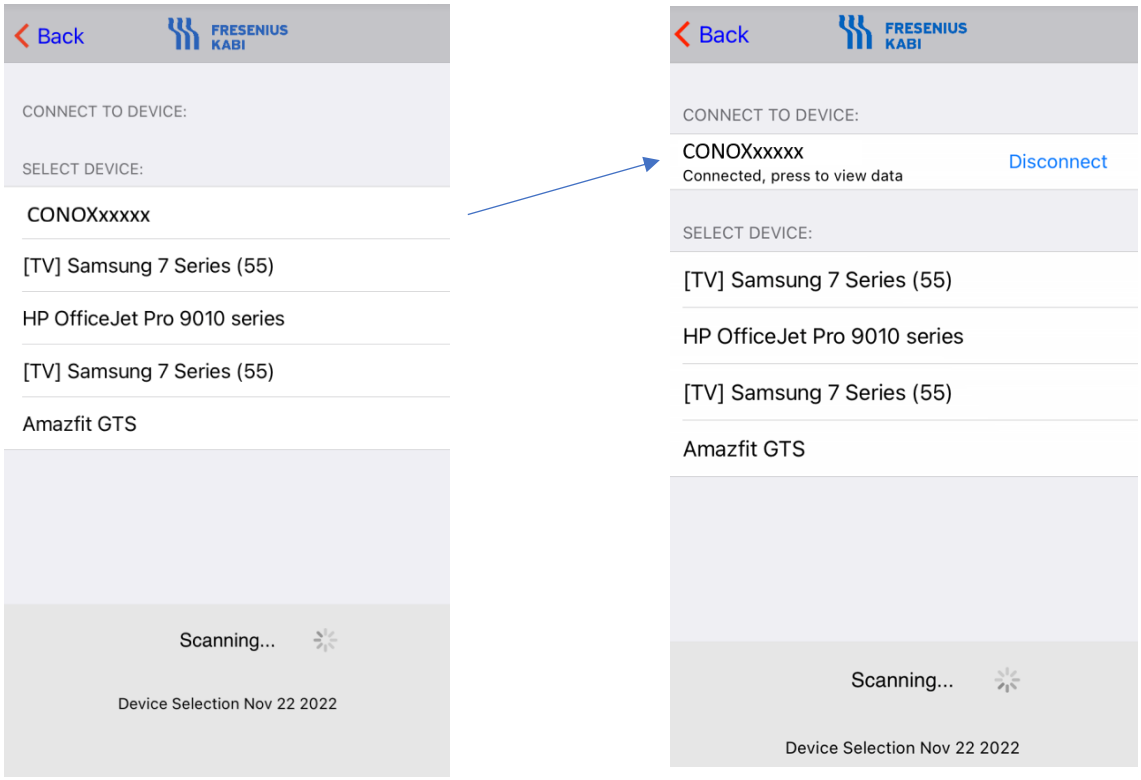
Select the Conox View iOS icon from the main screen of the iOS device.

When the Conox View iOS Application starts, the user must click on the 'Bluetooth' button. When pressed, it will display a new screen where the user may select the Conox

2D monitor device from a list of all available Bluetooth devices.
After the device is selected, its name should appear below the 'CONNECTED TO DEVICE' section of the screen.

Press on the name of the connected device to be redirected to the recording screen and automatically initiate a new recording.

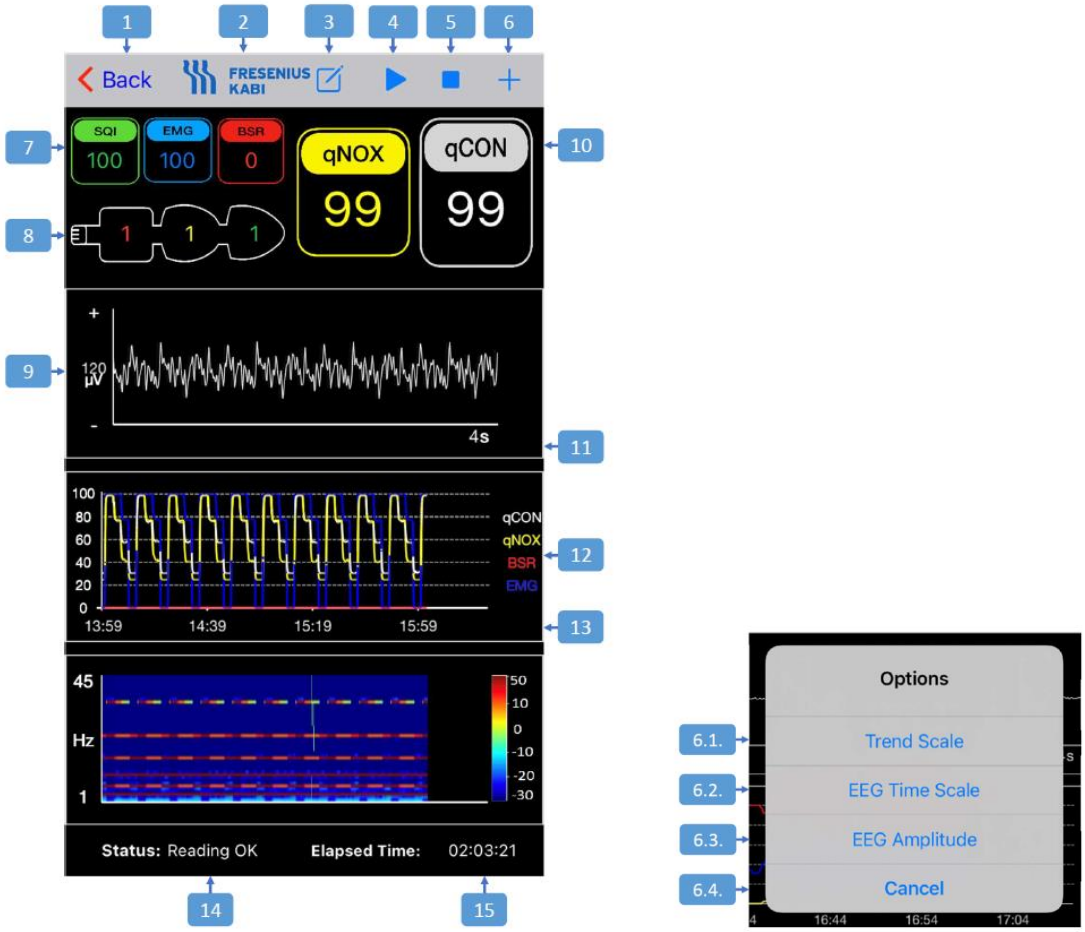
To disconnect the device, press the 'Disconnect' option that appears to the right of the name of the connected device and select a new device from the list.



Disclaimer: All other Bluetooth devices must be disconnected from the iOS device before connecting the Conox2D monitor. The use of the app connected to the Conox simultaneously with other Bluetooth devices that are transmitting data to the iPhone might cause unexpected behavior of the ConoxView.

5.2. USER INTERFACE DESCRIPTION

5.2.1. Initial Interface



1. Back button to go to the previous screen.
2. Fresenius Kabi logo.
3. Annotation box.
4. Start the recording.
5. Stop the recording.
6. 'Options' screen:
   - 6.1. 'Trend Scale' button
   - 6.2. 'EEG Time Scale' button
   - 6.3. 'EEG Amplitude' button
   - 6.4. 'Cancel' button

7. BSR, EMG and SQI Indexes.
8. Impedances of each electrode (in kΩ)
9. EEG voltage scale selector button.
10. qNOX and qCON Indexes.
11. EEG time scale selector button.
12. Index Trend Time Scale selector buttons.
13. Indexes time scale selector button.

14. Status bar.
15. Elapsed time from the beginning of the recording.

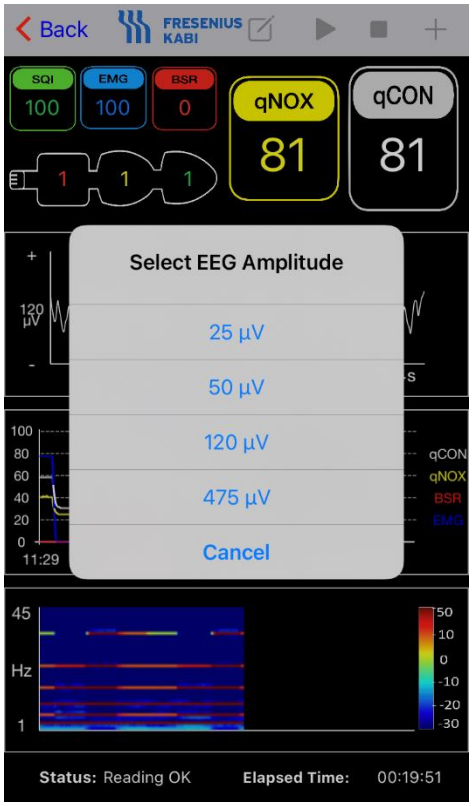
5.2.2. Changing the EEG signal scale

The EEG graph shows the voltage of the electroencephalographic signal received from the Conox2D monitor.

The default scale value is set to ±120µV. To show the available scales press the "EEG Amplitude" button. This button may be accessed in two ways:

- The 'Options' menu. This menu can be accessed through the '+' button located in the upper right corner of the recording screen.
- By clicking on the voltage label on the left side of the Y axis of the EEG graph.

Then press the chosen scale to change the Y axis scale of EEG signal.

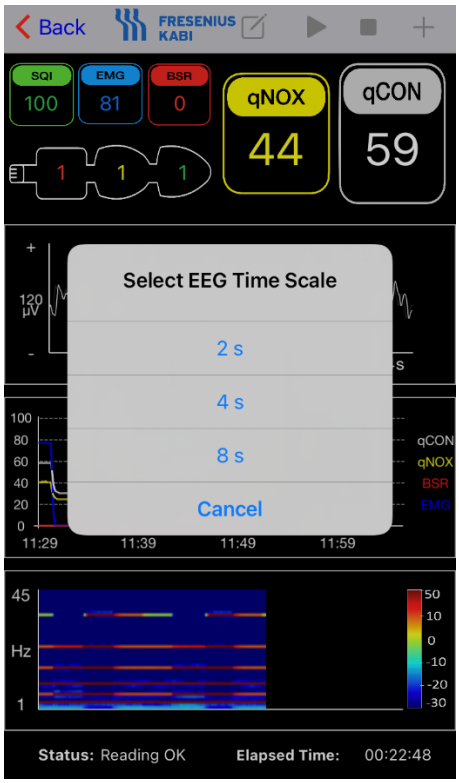


5.2.3. Changing the EEG signal time scale

The default scale value is set to 4 seconds. To show the available scales press the "EEG Time Scale" button. This button may be accessed in two ways:

- The 'Options' menu. This menu can be accessed through the '+' button located in the upper right corner of the recording screen.
- By clicking on the timescale label on the right side of the X axis of the EEG graph.

Then press the chosen scale to change the X axis scale of EEG signal.

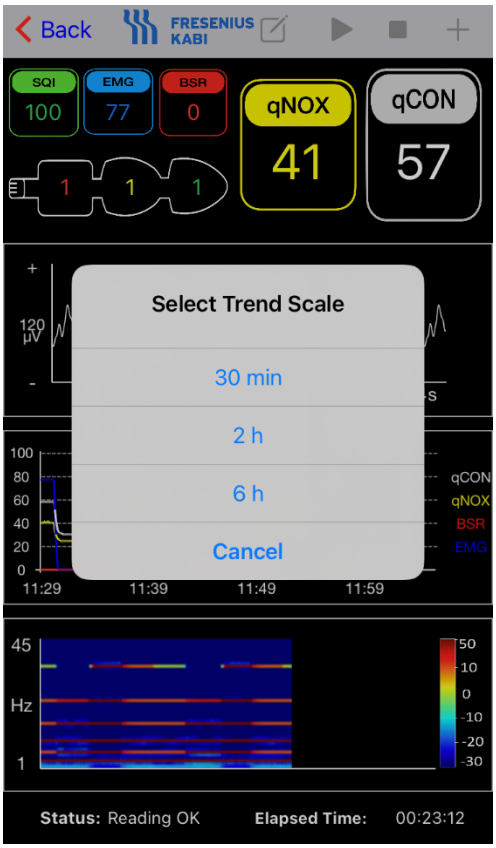


5.2.4. Changing the index trend signal time scale

The default scale value is set to 30 minutes. To show the available scales press the "Trend Scale" button. This button may be accessed in two ways:

- The 'Options' menu. This menu can be accessed through the '+' button located in the upper right corner of the recording screen.
- By clicking on the timescale label on the right side of the X axis of the Trends graph.

Then press the chosen scale to change the X axis scale of the index trends graph.

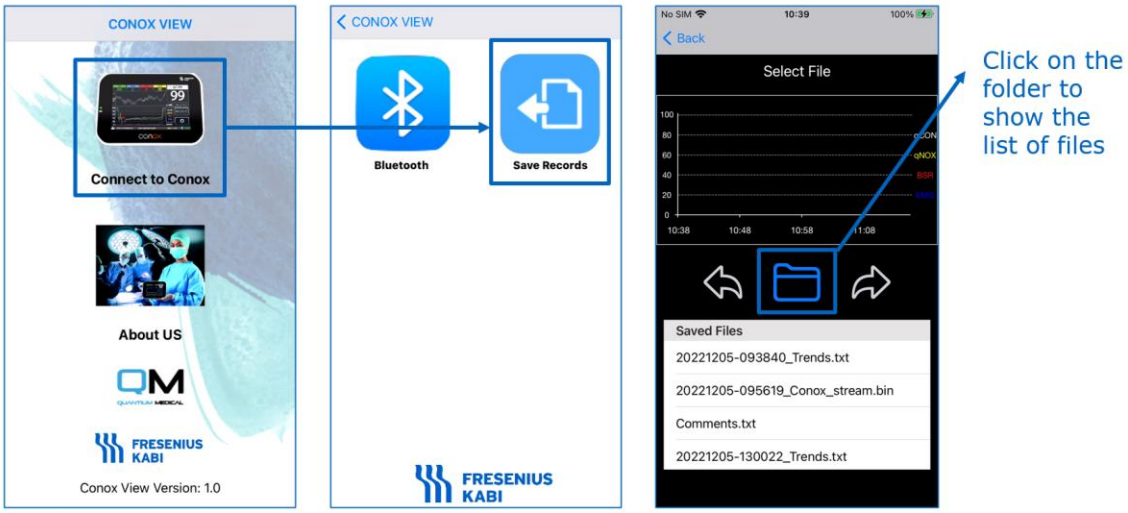


> After 6 hours of continuous recording, it is suggested to stop and restart the recording with the respective buttons. Recordings longer than 6 hours might cause instability of the ConoxView app.

5.2.5. 'Save Records' Button

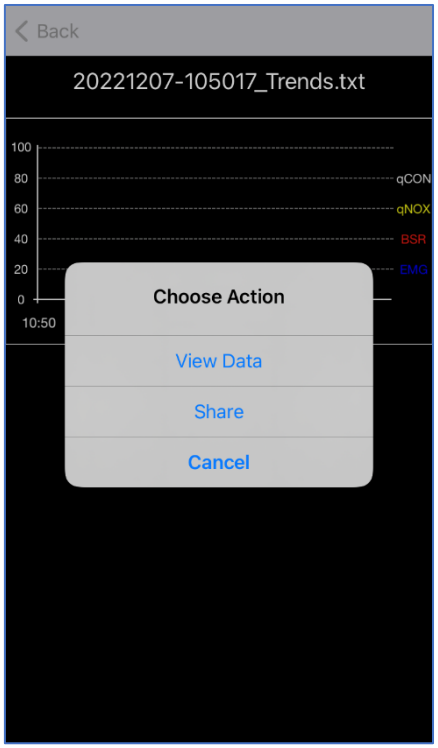
The 'Save Records' interface allows the user to visualize and share previous recordings. This button can be located following this route when opening the app:

'Connect to Conox' button → 'Save Records' button



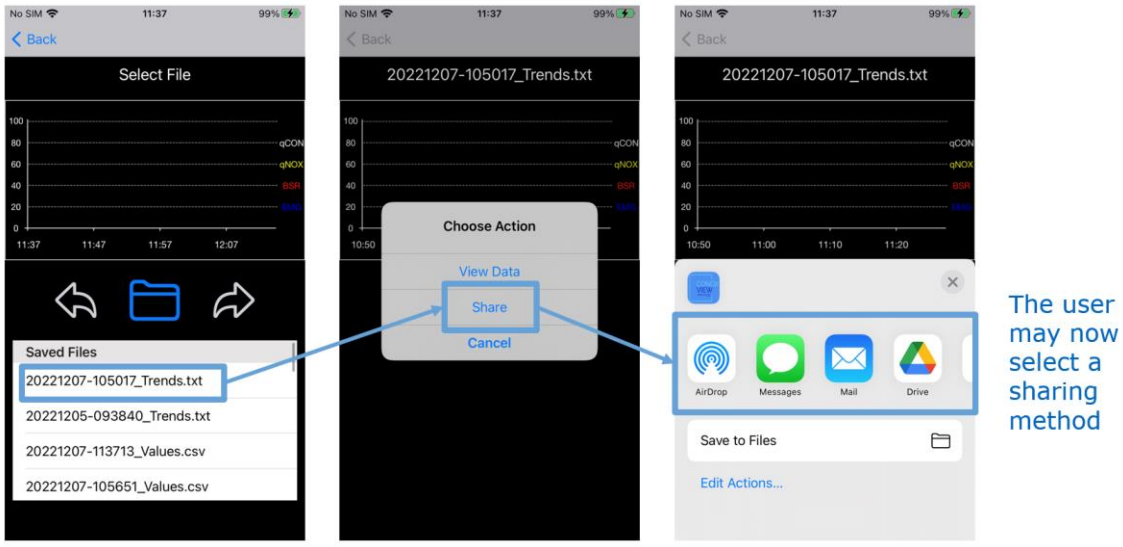
The user does not need to be connected to a Conox2D monitor via Bluetooth to access this functionality.

Clicking on the blue folder icon shows a list of all the available files.
Clicking any file will show the following menu:



- The **'View Data'** option allows the user to visualize _Trends.txt files, which will be explained below.

- The **'Share'** option allows the user to upload the file to a platform of their choosing.

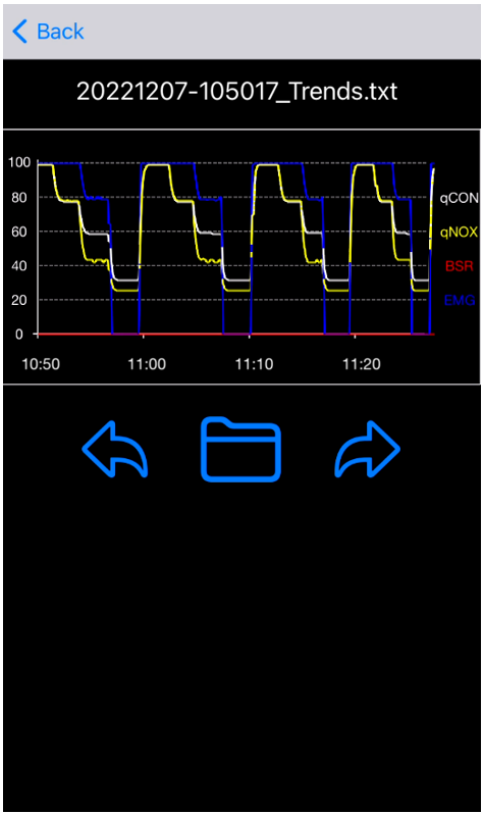


- The **'Cancel'** option allows the user to return to the previous screen.

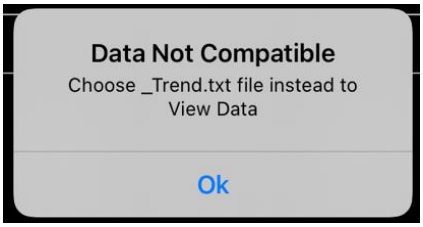
These are four types of files that may be generated during a recording:

- **YYYYMMDD-HHMMSS_Trends.txt files**
  - These files contain all the indexes values.
  - These files are the only ones available for visualization in the 'Save Records' interface.
    - Select any _Trends.txt file.
    - Then, select the 'View Data' option.

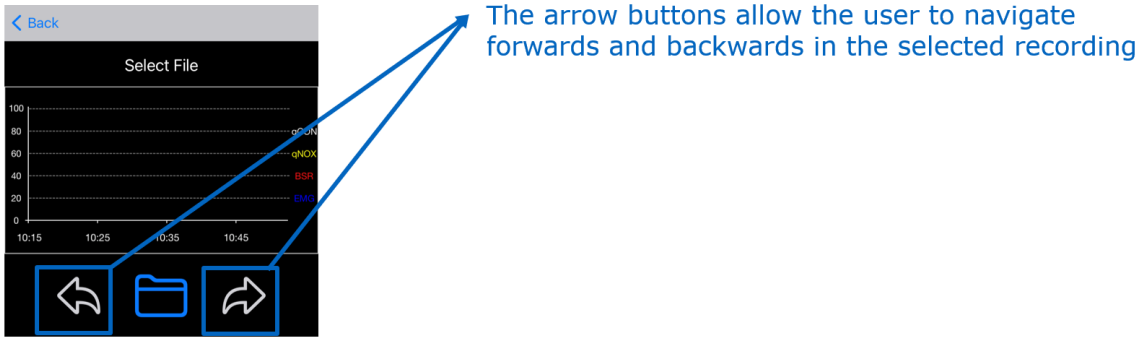
You will be able to visualize the trends graph of the recording:



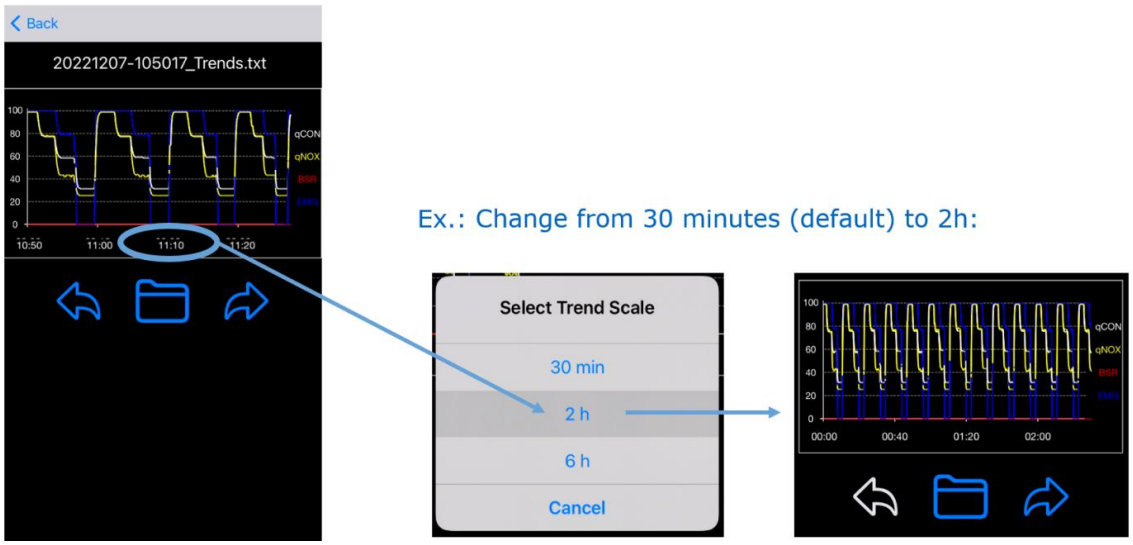
Selecting any other type of file will raise the following alert:



  - The user may navigate the recording using the arrow buttons once the _Trends.txt file has been selected for visualization:



- The user may change the scale of the trends graph by pressing on any time scale label:



- **YYYYMMDD-HHMMSS_Values.csv files**
  - This type of file is only generated when the user selects a _Trends.txt file for visualization.
  - This file contains the index values and the comments left by the user during the recording in a table format.
  - It can be shared but cannot be visualized through the 'Save Records' interface.

- **YYYYMMDD-HHMMSS_Conox_stream.bin files**
  - This type of file contains the stream of binary data generated by the recording.
  - It can be shared but cannot be visualized through the 'Save Records' interface.

- **Comments.txt files**
  - This type of text file contains the notes left by the user during the recording.
  - The user may visualize the content of this type of files through various

methods:

- The comments are saved in the _Values.csv file in a separate column.
- The comments are stored in the iOS device 'Files' folder (Refer to the FILE STORAGE section)

5.2.6. The 'Device Info' Button

This button opens a screen that contains vital information about the iOS app as well as the Conox2D device that is currently connected to your iOS device, such as:

- The manufacturer name (Quantium Medical)
- The Conox2D model number
- The Conox2D serial number
- The hardware revision code
- The firmware revision code
- The iOS app version

The 'Device Info' button may be accessed through the 'Back' button on the upper left corner of the recording screen.

> Please be aware that pressing the 'Back' button in the middle of a recording will stop the recording.

5.2.7. Select 'Conox' Button

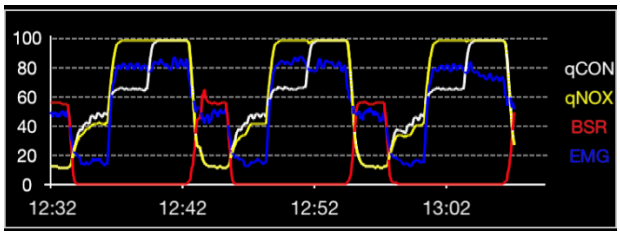
This button displays the list of the Conox monitors that are detected by the iOS device in order to select a Conox monitor to connect with and start the recording.
This process can be done:

- before starting the recording
- if the selected Conox monitor is disconnected when the application is initialized
- if the user has closed the list of paired Conox monitor

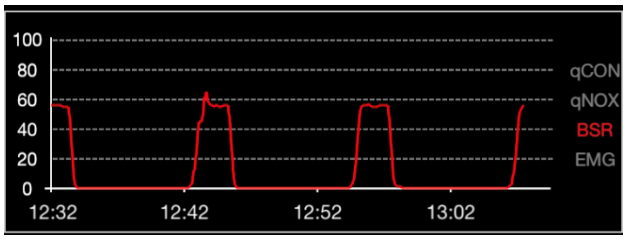
Once the recording is started and the Conox View has begun to receive data from a Conox monitor, this button is disabled. In order to switch to another Conox device when the recording has started, stop the recording by using the 'Back' button, go back to the main screen, disconnect the current device through the 'Disconnect' button and select a different Conox2D monitor from the list of available devices.

5.2.8. 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 tapping on the respective index legend. The legend is located on the left side of the trends graph.

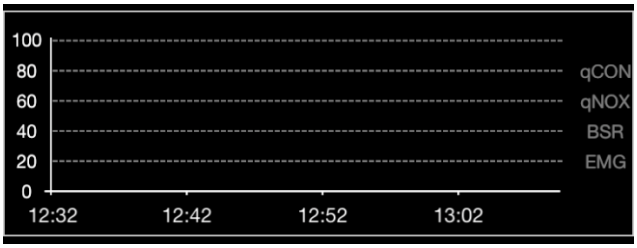


Trends graph with all the indexes selected



Trends graph with only the BSR index selected.

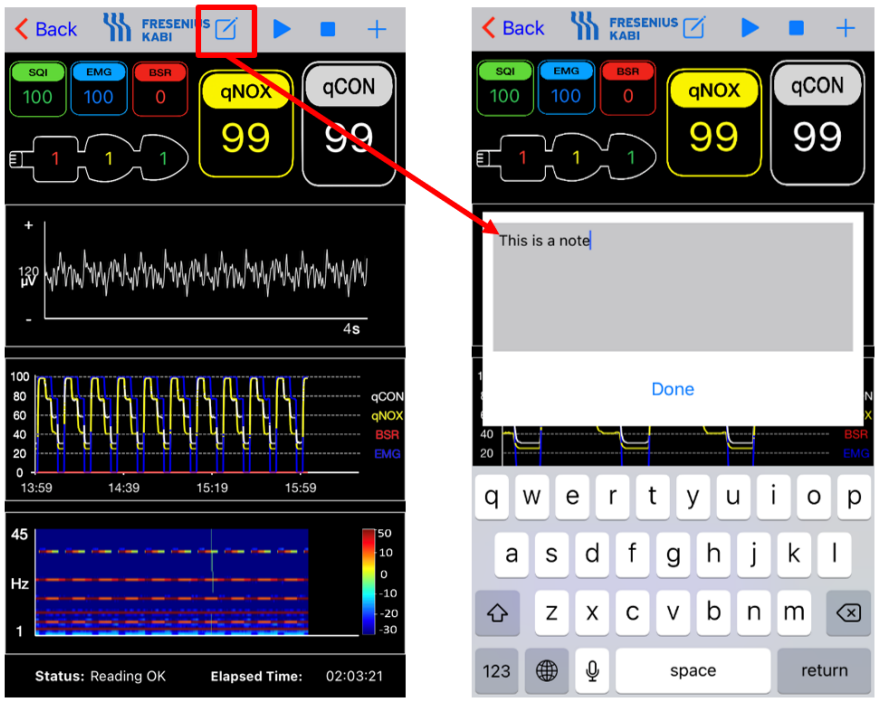
When the index is displayed on the graph, the color of the index legend name is the respective color of the index, while when an index is not displayed on the graph, the color of the index legend name is grey.



Trends graph with no indexes selected

5.2.9. The Annotation Box

To make an annotations in the log file, press the 'Annotation' button, located on the upper part of the recording screen. Afterwards, the keyboard is shown in the screen. The annotation is saved in the log file when the button "Done" is pressed.



5.2.10. 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).
It also shows the elapsed time since the recording was initialized.

5.2.11. The Exit Button

The correct way to exit the application is to use the 'Stop' button located on the upper part of the interface, which can be found to the right of the Fresenius Kabi logo.

Then, press the 'Back' button located on the upper left corner of the recording screen in order to stop the recording and then exit the application by pushing the exit button in the lower part of the iOS device. This button may vary from one device to another

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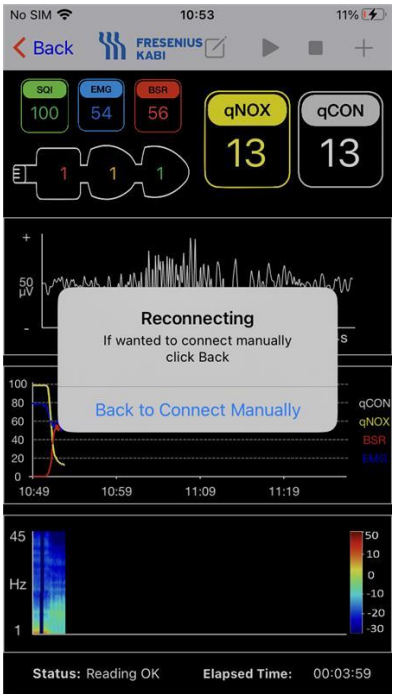
6. MESSAGES

6.1. 'Reconnecting' Message

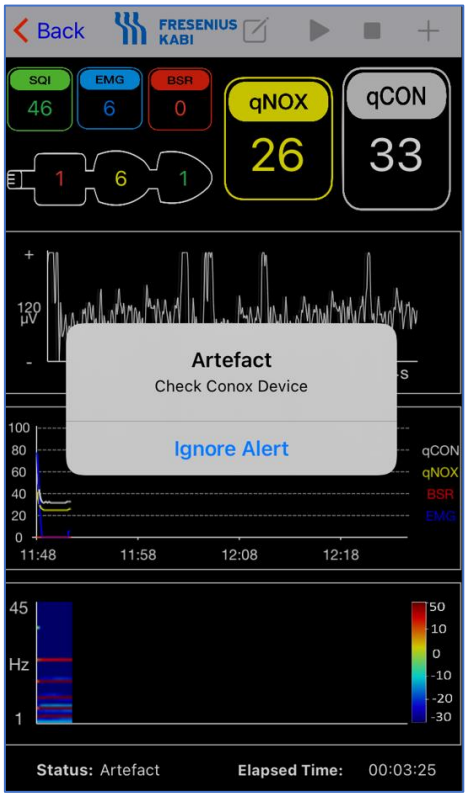
The message 'Reconnecting' is shown in the event of not receiving any data from the

Conox monitor.



6.2. 'Artefact' Message

The artefact message is displayed when the Conox monitor detects artefact and stops when the Conox ceases to detect an artifact.

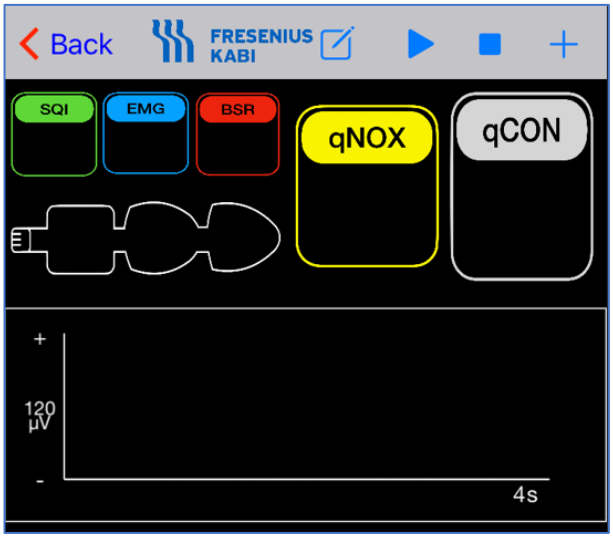


This event is logged every second in the Conoxlog file.

6.3. ‘Impedance Check’ Message

The impedance check message is displayed in the status bar during every impedance measurement that is made by Conox monitor, which happens every 15 minutes and lasts for a few seconds.

You might notice that the electrode impedance indicators as well as the EEG graph and the index indicators appear blank for a few seconds: this means that the Conox 2D monitor has just finished an impedance check.
The data will reappear as soon as the impedance check finishes.



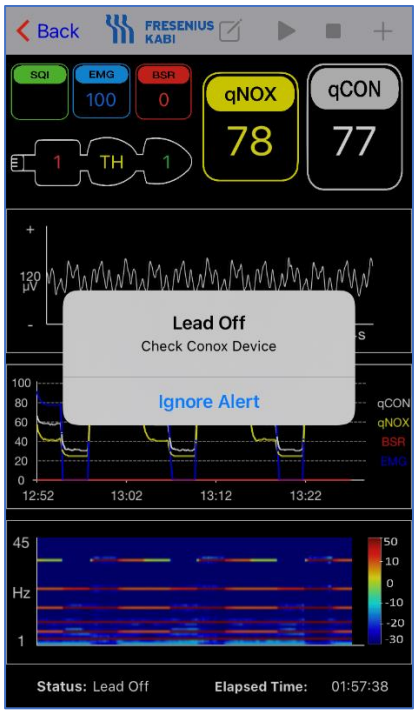
This event is logged every second in the Conoxlog file.

6.4. ‘Lead Off’ Message

The ‘Lead Off’ message is displayed in the screen as well as in the status bar while the Conox monitor detects no signal in any or some of the electrodes of the patient cable. Plausible reasons for the appearance of this message include:

- The patient cable is disconnected. Connect the cable.
- The connection between the electrodes and the patient’s skin is poor. Clean the patient’s electrode area.
- The patient cable is defective. Change the cable.
- The electrode set is defective and must be replaced.
- The Conox 2D monitor is defective. Contact your manufacturer.

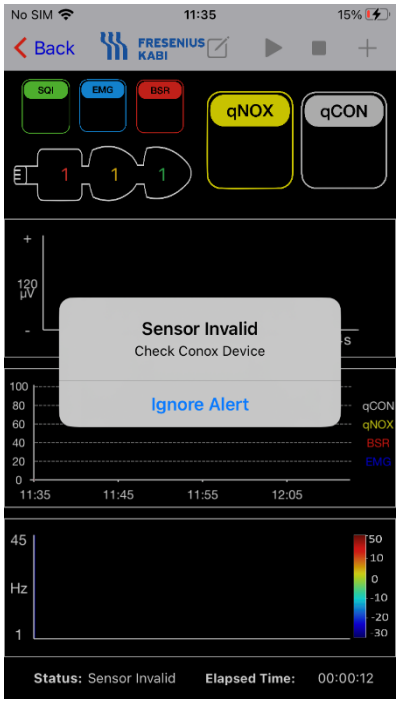
This event is logged every second in the Conoxlog file.



6.5. 'Invalid Sensor' Message

The 'Invalid Sensor' message appears when the electrodes that are currently in use are not official. Official electrodes have a unique electronic identifier.

Replace the current electrodes for a valid set. If this message appears when official electrodes are connected, contact the Manufacturer.



6.6. 'Sensor end of use' Message

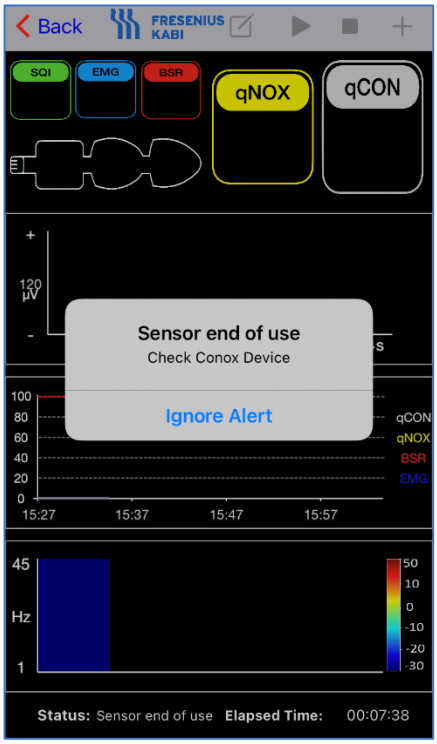
This message appears when the electrodes that are currently in use have surpassed their

usage time (24 or 32 hours) and thus must be replaced for a new set.

If the index labels still show their respective values when this message appears, it means that the set of electrodes connected to the Conox monitor are valid but should be replaced because:

- They might be expired. Check their validity date.
- They might have surpassed their recommended usage time (24h maximum) and must be replaced. This happens when the electrodes have been connected between 24h-32h.

If the index labels do not show their respective values when this message appears, it means that the set of electrodes currently connected to the Conox monitor has been used for 32h or longer and must be replaced immediately.

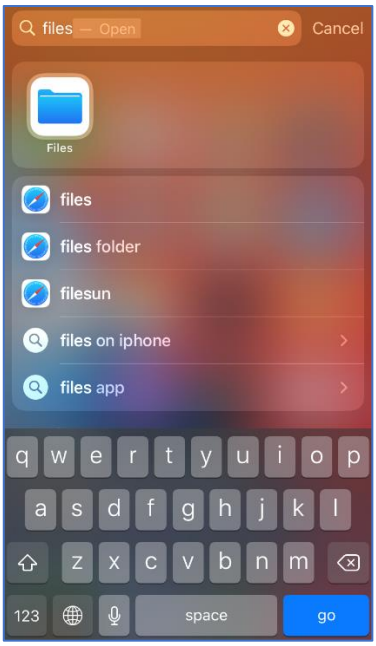


7. FILE STORAGE

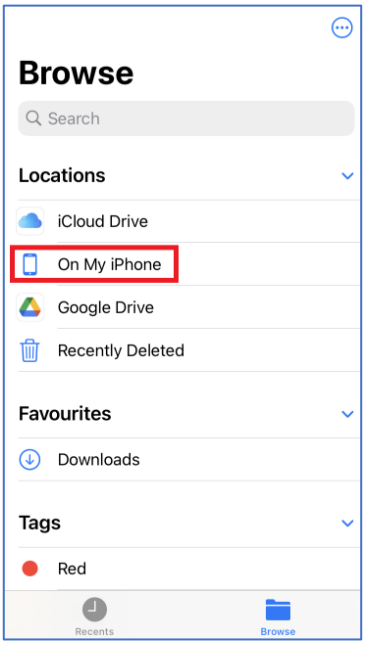
7.1. LOCATION OF STORED FILES IN THE iOS DEVICE

The files are automatically stored after each recording in the Conox View folder, located in the 'Files' app of your iOS device.

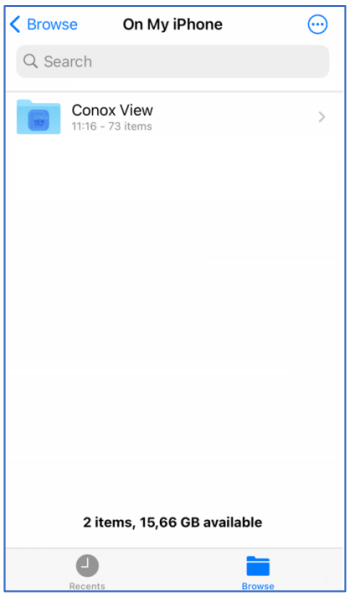
To access the 'Files' app, look for its icon on your device's main screen.
If you cannot find it, access it through the search bar by scrolling down once in the main screen of your iOS device. Once the search bar pops up, write 'files'. The app should come up on the first result.

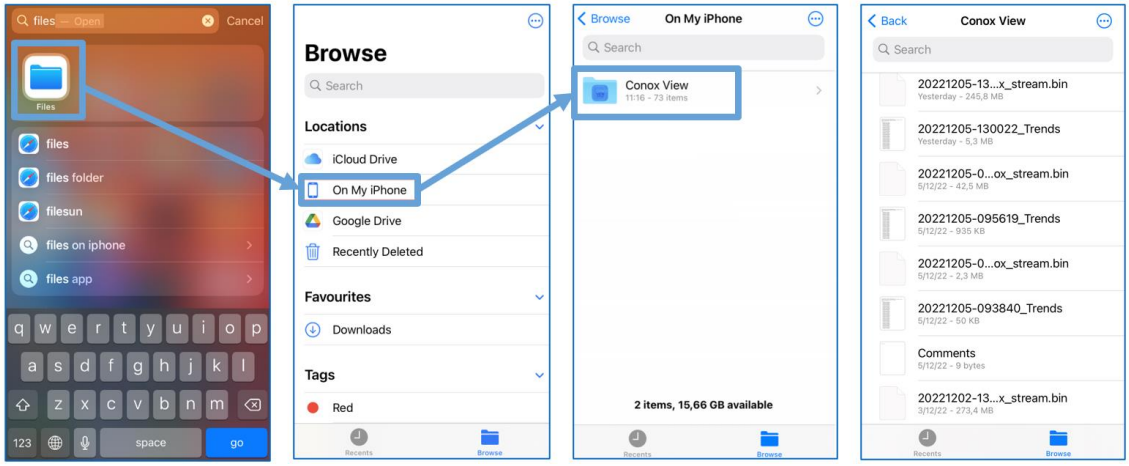


Once in the 'Files' app, go to the 'On My iPhone' location.



Once in the 'On My iPhone' location, look for a folder called 'Conox View'. This folder is where all the recordings are stored.





7.2. COPY FILES STORED IN THE iOS DEVICE TO A PC

There are several ways to transfer the files from your iOS device to your PC, which will be described below:

<u>Option 1. Through a cloud storage application</u>

Download the chosen cloud storage app from the App Store and log in to your account. These might include, but are not limited to:

- Google Drive
- Dropbox
-

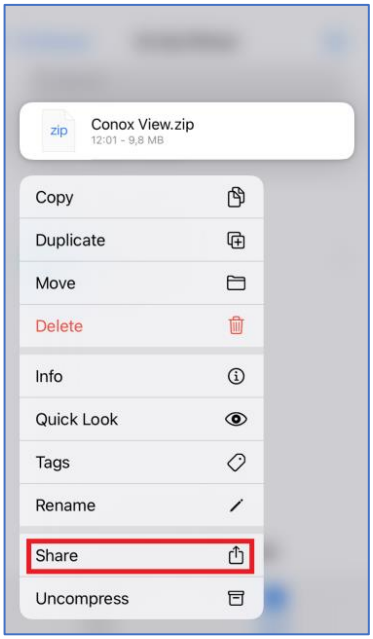
You may either upload all of the saved recordings to your cloud storage account or select a specific recording.

<u>To upload the whole folder of saved recordings:</u>

1. Follow the steps in section "Location of Stored Files in the iOS Device" to access the 'Conox View' folder.
2. Press long enough on the 'Conox View' folder icon until a menu pops up. Then, click

on the ‘Compress’ button from said menu. This action will create a compressed version of the folder.

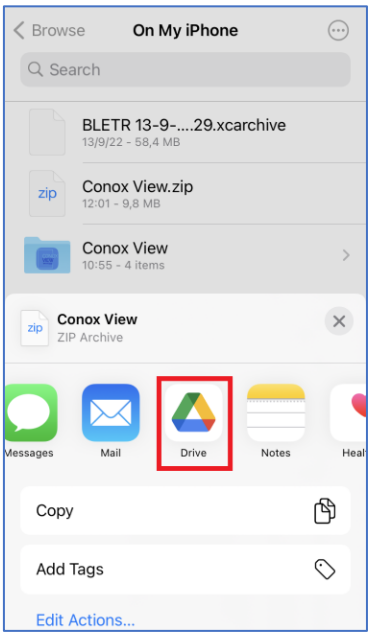
3. Once the compressed file has been generated, look for it. The compressed file should be named ‘Conox View.zip’. Then, once again, press long enough on its icon until a menu pops up.
On said icon, press on the ‘Share’ button.



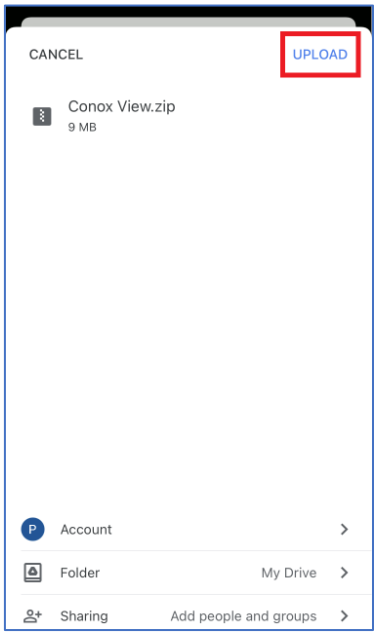
4. After pressing ‘Share’ a menu will appear, in which the user will be offered a variety of sharing methods. To share the files through a specific cloud storage app, click on its respective icon.

   The remaining steps are specifically meant to guide you through the file upload procedure using Google Drive.

These steps may vary for different third-party cloud storage apps.



5. The user's Google Drive account main folder will appear after doing the last step. Here, the user may choose the folder in which they wish to store the Conox View .zip file. Once it has been chosen, the user must press 'UPLOAD'.



After completing this last step, the files should be able to be accessed through any device that has access to the user's Google Drive account.

In order to access this .zip file from your PC, simply log in to your Google account from said computer and look for the 'Conox View.zip' file in your Drive folder.

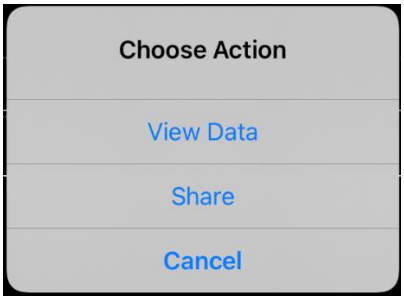
You may now download the file and decompress it in your computer in order to access the recordings.

To upload one specific file:

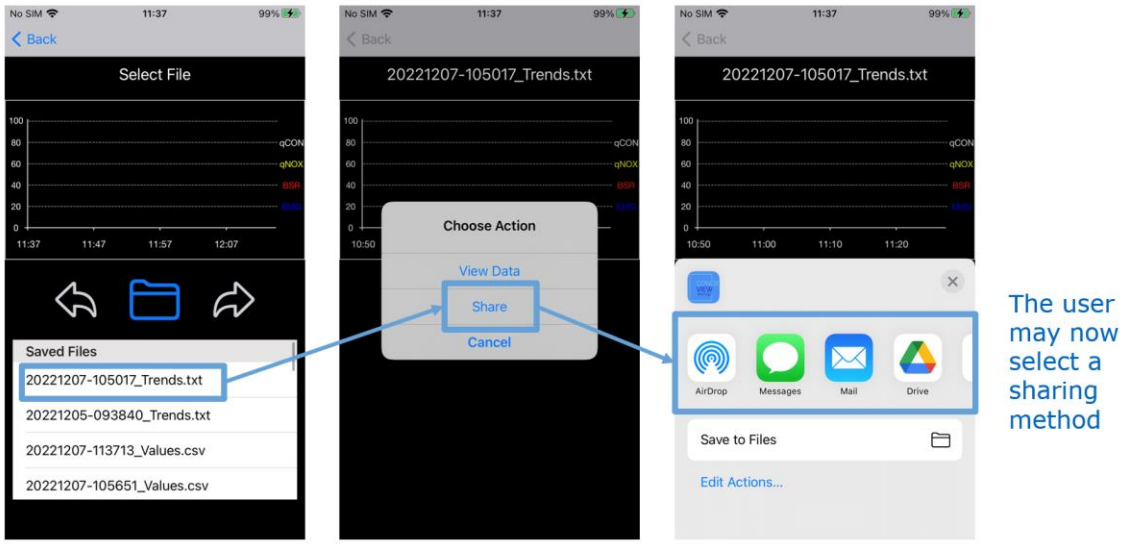
1. Open the ConoxView iOS app and select 'Connect to Connox'.
2. In the next screen, select the 'Save Records' button.
3. Click once on the blue folder icon.
4. A list of all saved recordings will show up. In this list, you will find up to 4 types of files for each saved recording (Refer to section: 'Save Records Button')

   Select the file that you want to transfer to your computer.

5. The following menu will show up:



Select 'Share'. A menu containing all possible sharing methods will show up. Press on the app that you wish to use to share the previously selected file.



Depending on the cloud storage application selected, the remaining steps to upload said file to the cloud may vary.

Option 1. Through iTunes

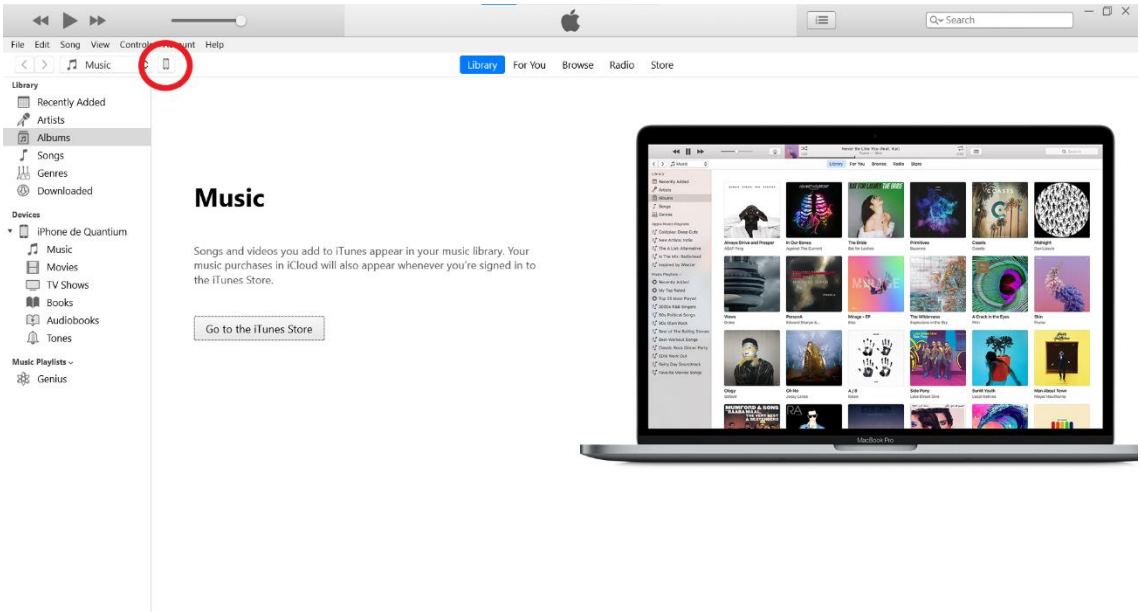
1. Download the iTunes program through the official Apple webpage: https://www.apple.com/es/itunes/

2. Select the appropriate version for your software (Windows or macOS) and make sure to have the latest update.

3. Install the program following the steps of the iTunes installation wizard.

4. Open the iTunes program and connect your iOS device through a USB cable.

   Once connected, a small icon resembling an iOS device should appear on the top left corner of the screen:

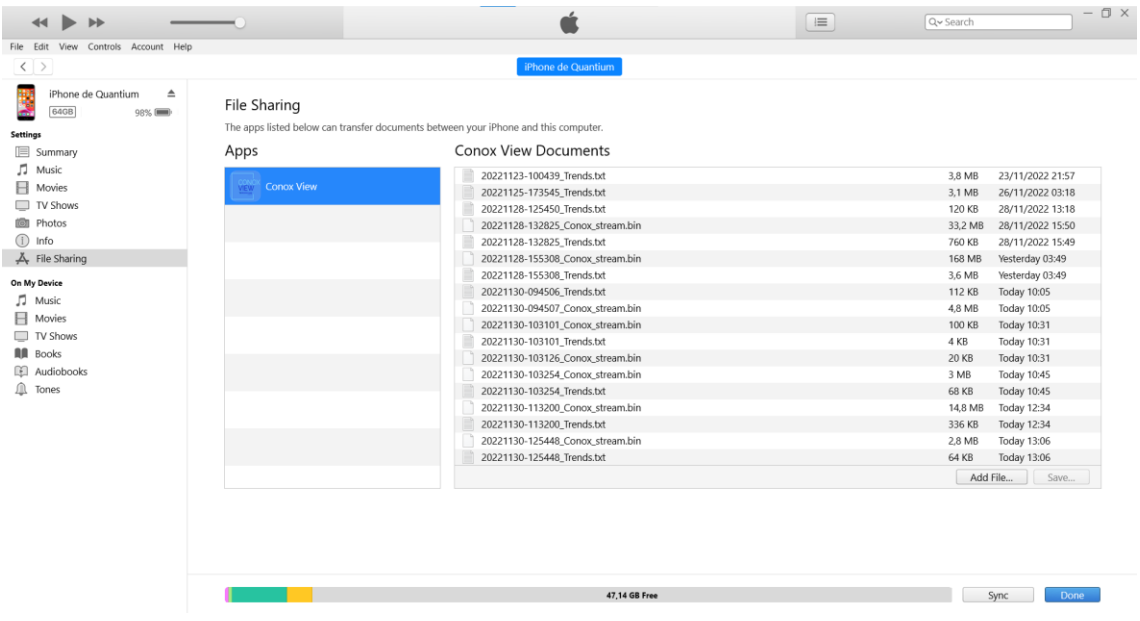


   Click on said icon.

5. A menu will show up to the left of your screen. From this menu, select the 'File Sharing' option. This will open up a list containing all the available apps to transfer files from your iOS device to your PC.

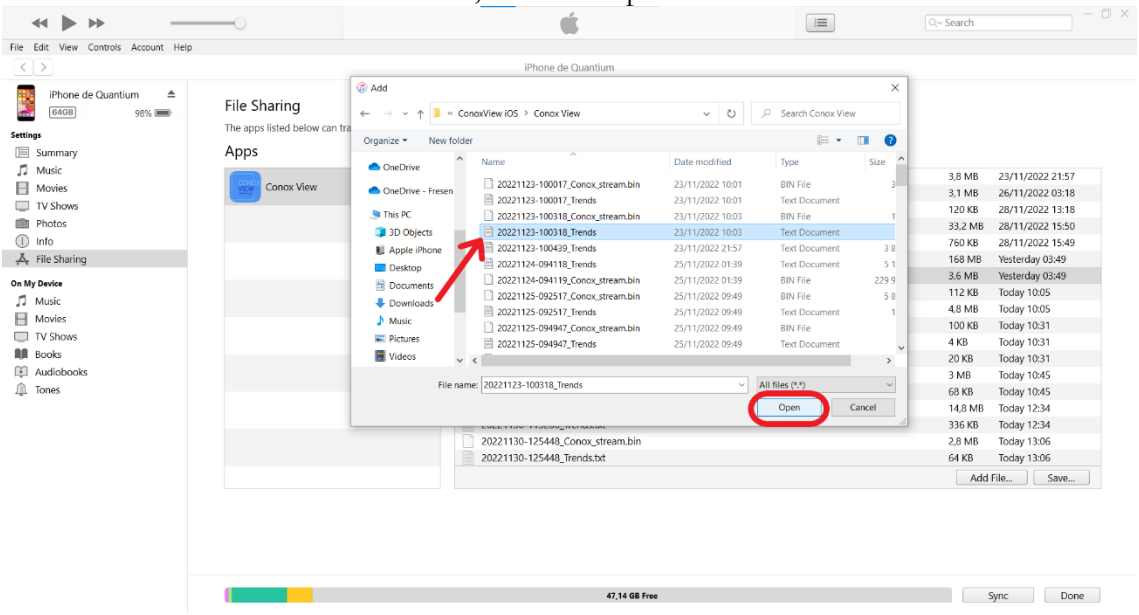
   From this list, select the 'Conox View' app.

6. This will allow you to select one or more recording files and save them to your PC: simply select the file you wish to transfer and click on the 'Save…' button.



If you wish to visualize older recordings in the ConoxView iOS app, you may add add said files here and they will automatically appear in your ConoxView iOS app.

In order to do so, click on the 'Add File…' button and select the files from your PC.
Once the desired file is selected, click on 'Open'.



Disconnect the iOS device from your computer and close the iTunes program.

You may now visualize them on the 'Saved Records' interface from your ConoxView iOS app.

8. SPECTROGRAM

Conox View shows the spectral density array as an image on the user interface. The spectrogram is available all the time scales: 30 minutes, 2h and 6 h 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
- In the x axis, the last 30 minutes, 2h or 6h of recording, depending on the selected time scale

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