FRESENIUS KABI

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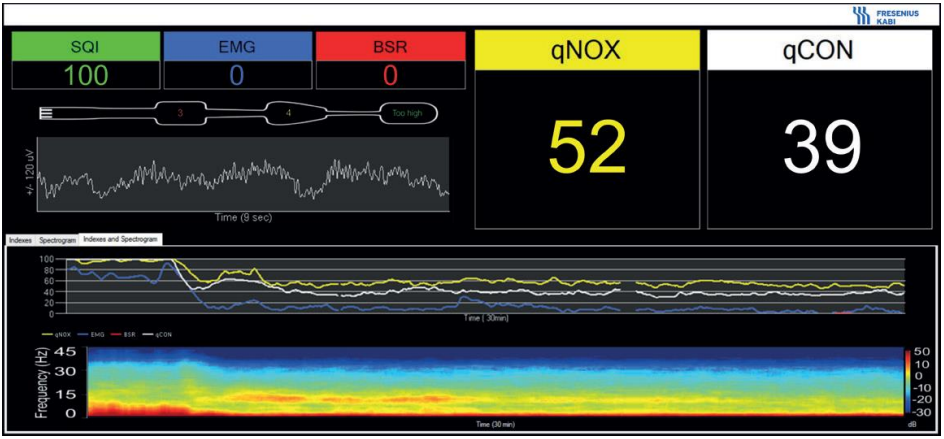
ConoxView PC v3.2

Instructions for Use



Abbreviations

EEG	Electroencephalogram
PC	Personal Computer

Table of Contents

1. General Information

1.1. About this manual

This manual contains important information about the operation of the ConoxView (the "Software") PC v3.2. Here you will find how to install and operate the Software. It is important that you read and understand the manual
fully before using the Software.

Ensure that all users of the Software are suitably trained and qualified, and make sure that the user has access to this manual.

1.2. Contact address

Manufacturer
Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg
Germany
+49 (0) 6172 / 686-0
www.fresenius-kabi.com

1.3. Disclaimer

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1.4. Copyright

2. Software requirements

The application ConoxView PC was designed to run on medical grade computers and monitors running Microsoft Windows Operating System, with the following minimum requirements:

Minimum Requirements	
Operating System	Windows 10 (64 bits)
Connectivity	Bluetooth connectivity
Screen size	10 inches
Memory	ROM: 1024MB RAM: 1024MB
Processor	1GHz

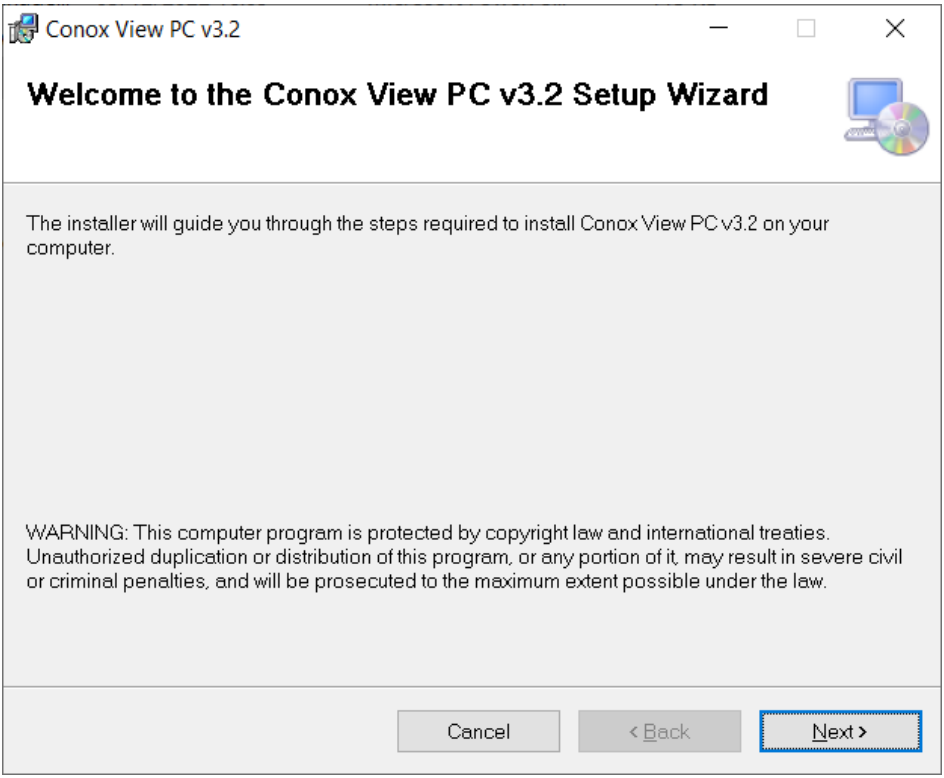
Due to the wide variety of manufacturers and software, Quantium Medical cannot guarantee that the application will run on all computers that meet these requirements. Contact your Distributor for further information if encountering problems. It is recommended that no other programs are open during the functioning of the ConoxView to ensure a good performance.

3. Installation

3.1. Installation of the software

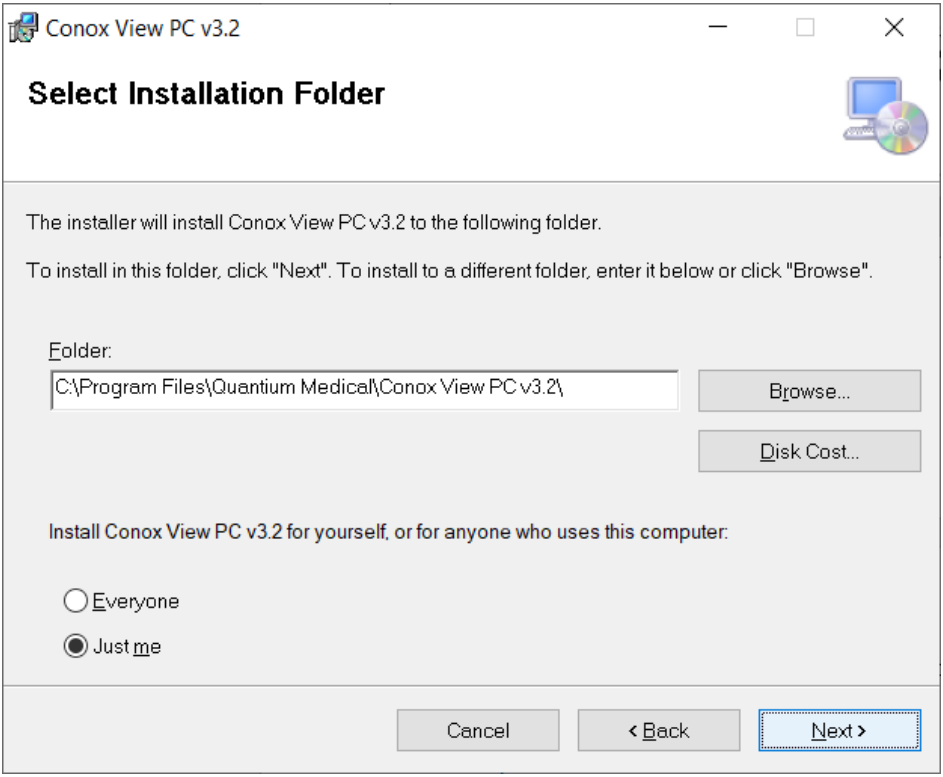
Install the Software via the ConoxView PC v3.2 icon.

The installer will guide you step by step. Follow the recommendations and continue the installation. Click on “Next”.

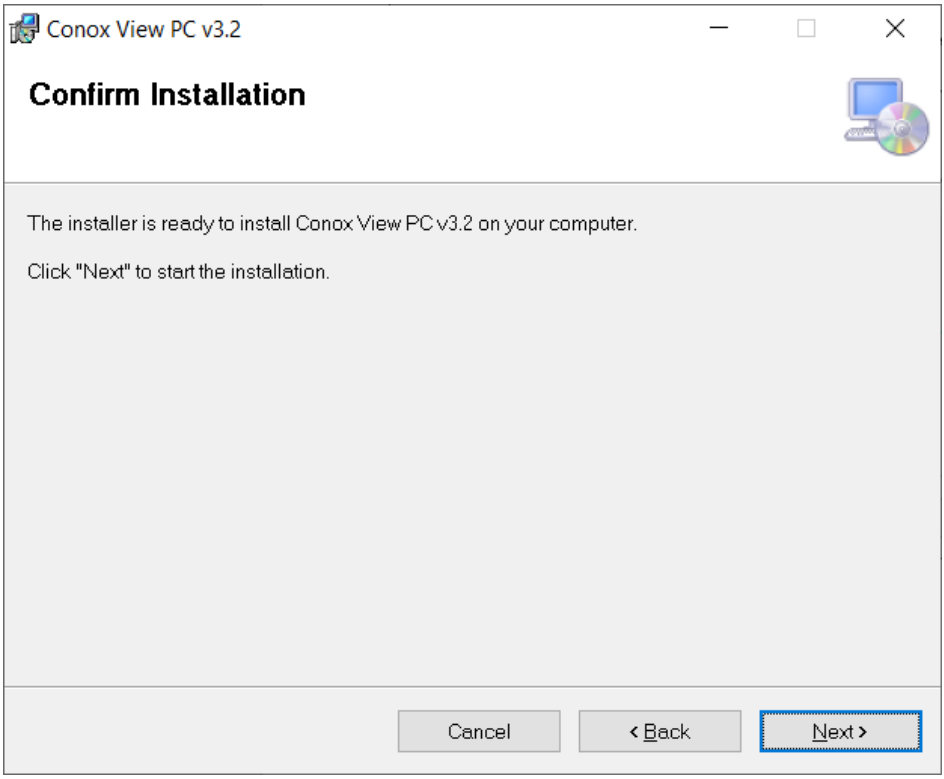


By default, the installer will propose a folder on the user’s PC to save the program files.

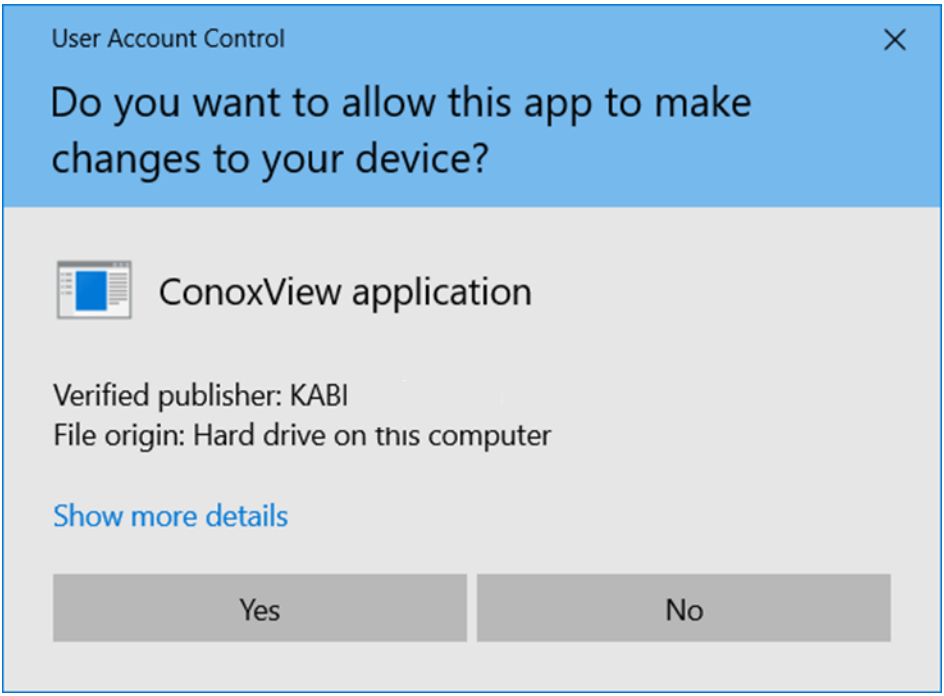
The user can change this by clicking on the “Browse...” button. Once the folder is selected, click on “Next”.



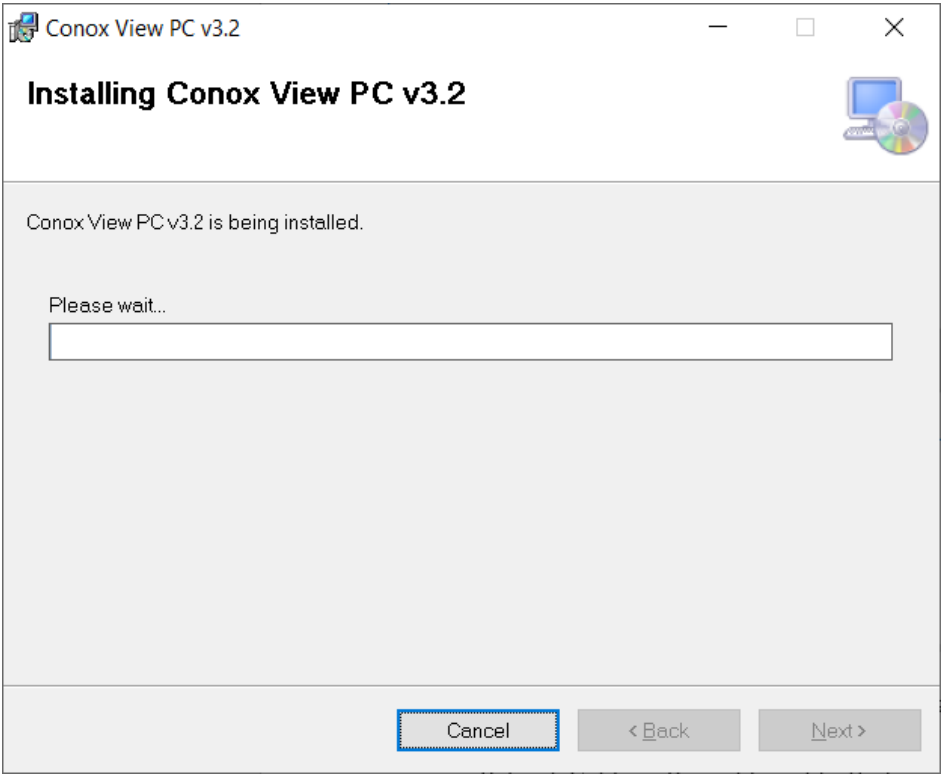
Confirm the installation.



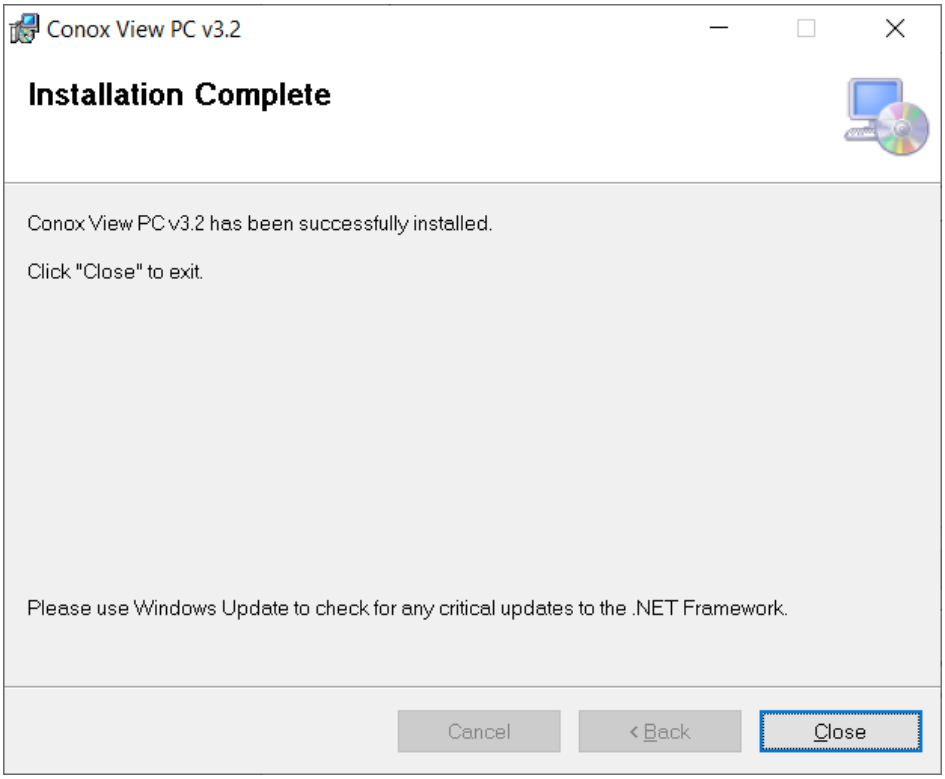
Click on the “Yes” button



Wait until the installation is completed



Once the installation is completed, the following notification will appear and a shortcut on the desktop will be created. Click on “Close”. ConoxView software is now installed on your PC.



3.2. Pairing the Conox

1. Enable the Conox Bluetooth®.
2. Enable your device's Bluetooth® and find the Conox.
3. Select the Conox through the serial number.

If a password is required, please contact your local distributor to obtain this information.

Note: If PC displays two devices with the same serial number, the PC shall be paired with the device that shows the icon.

4. Software characteristics

4.1. System description

The ConoxView reads data received from the Conox via Bluetooth and extracts information about the indices, impedances, Conox status and EEG signal. The Software allows the user to save annotations and notes while the Conox is recording patient data.

4.2. Controls and indicators

Description	
1. Tabs	7. Trends graph and spectrogram image
2. Toolbar	8. Annotations
3. Main indexes	9. Status bar
4. Secondary indexes	
5. Electrode impedance	
6. EEG graph	

4.3. Tabs

Tab	Description
New case	Record and visualize a case in real time
Previous cases	Visualize the cases saved on the PC
Download data from Conox	Send recorded cases stored on the Conox to the PC

4.4. Toolbar

The toolbar contains buttons that allow the user to save and adjust the visualization of the case:

Tab	Icon	Description
Save		Allow recording while the case is being displayed. Options: Save file ON / OFF
Full screen		Display the case in full screen mode
Play		Start visualizing the case
Stop		Finish recording/visualizing the case
COM Port		Select serial port communication for Bluetooth® connection
EEG graph amplitude		Select EEG graph amplitude (µV). Options: +/- 25uV, +/- 50uV, +/- 120uV, +/- 250uV and +/- 475uV
EEG graph timescale		Select EEG graph timescale. Options: 3, 6 and 9 seconds.
Select index trend		Select graphs to trend. Options: qCON, qNOX, EMG, BSR
Trend time scale		Select trends graph and spectrogram timescale. Options: 30 min, 2h, 6h.
Filename		Name of file currently being recorded.
Information		Information window of the software.

4.5. Main Indexes

Index	Color	Range
qCON	White	0-99
qNOX	Yellow	0-99

4.6. Secondary Indexes

Index	Name	Color	Range
BSR	Burst Suppression Rate	Red	0-100
EMG	Electro-myogram	Blue	0-100
SQI	Signal Quality Index	Green	0-100

4.7. Electrode Impedance

Name	Electrode color	Range
Neg Imp	Red	0-10, Too High (TH)
Ref Imp	Yellow	0-10, Too High (TH)
Pos Imp	Green	0-10, Too High (TH)

4.8. EEG waveform

Graphical representation (downsampled) of the EEG waveform.

4.9. Trends graph

Graphical representation of the qCON, qNOX, BSR and/or EMG

4.10. Spectrogram

Graphical representation of the EEG signal frequency content. The spectrogram is represented in a two-dimensional way as a function of time and frequency (1 – 45 Hz) and the power of the signal is color coded. Being the blue the lowest proportion of encephalographic waves and the red the highest.

The spectrogram is available in the 3 time scales: 30 min, 2 hours and 6 hours, 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 minutes, 2 hours or 6 hours of recording

The user can select the view of index trend and spectrogram by three tabs (figure c) that show:

- only the index trend graph,
- only the spectrogram,
- both the index trend graph and spectrogram.

The "Indexes" tab contains only the index trend graph, the spectrogram tab contains a spectrogram box that shows only the FFT image, the index and spectrogram tab contain two boxes: one shows the index trend graph and the other shows the FFT image.

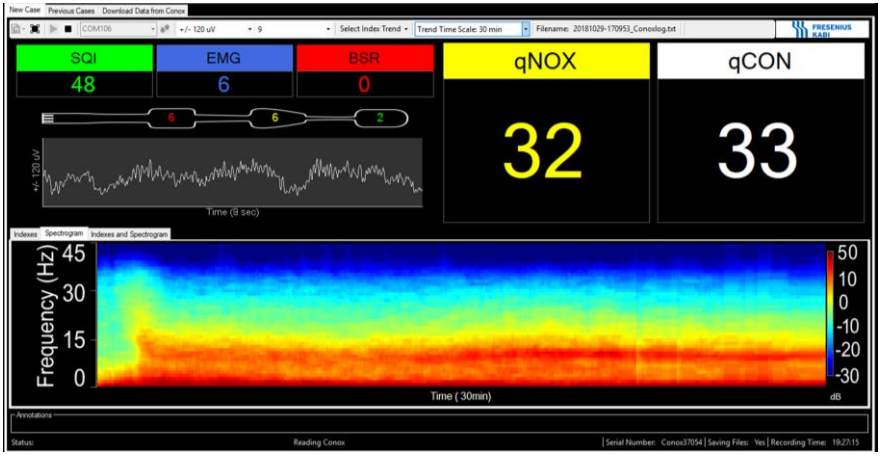


Figure a

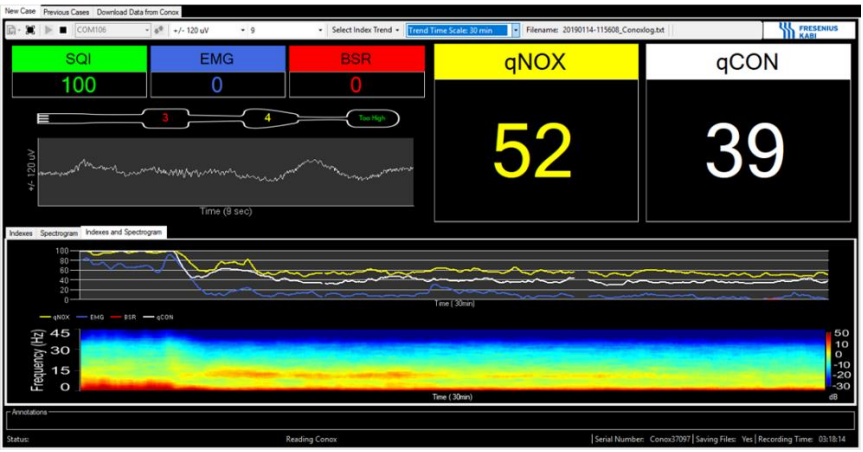


Figure b

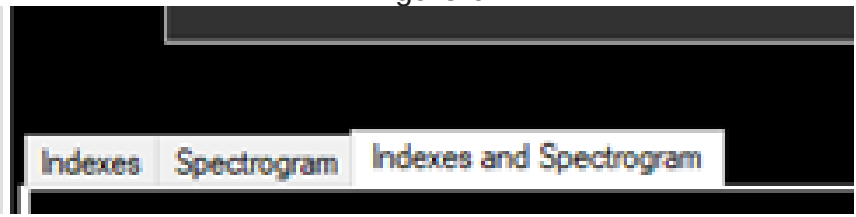


Figure c

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 $\sqrt{2}\,\mu V$

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*√2	102400	50	
3.24*√2	10.49	10	
1*√2	1	0	
0.32*√2	0.1024	-10	
0.10*√2	0.01	-20	
0.031*√2	0.00096	-30	

4.11. Recording Time

Indicates the time the ConoxView has been recording the case. It does not have to match with the elapsed time.

4.12. Annotations

Text box to make notes and write any event occurrences during recording.

ConoxView does not ensure the protection of personal data entered into the system.

4.13. Status bar

The status bar contains the following information:

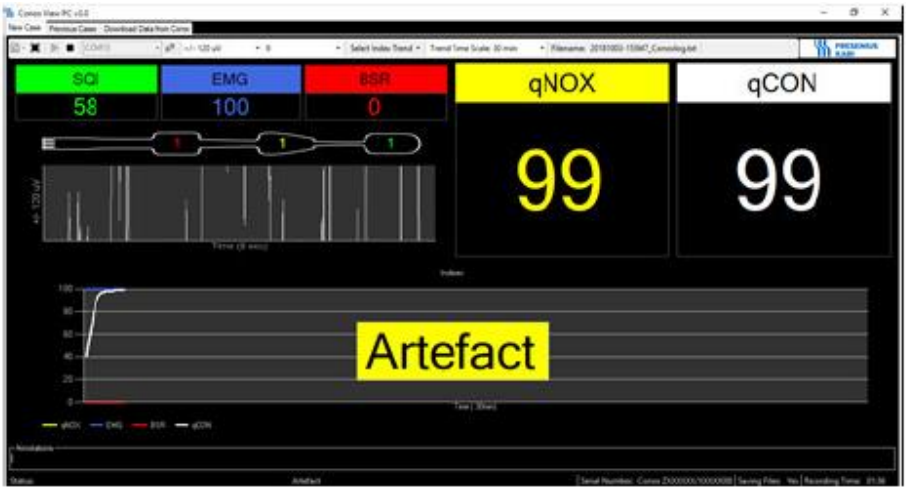
Name	Description
Status	Software operational status: Reading Conox, Artefact, Impedance Check, Lead Off, No Data Received from Conox.
Serial number	Serial number of Conox transmitting data
Saving files	Indicates whether the file displayed on the screen is being saved
Recording time	Time ConoxView has been recording the case displayed on the PC

4.14. Notifications and warning messages

The ConoxView PC displays the following notices and warning messages during data acquisition:

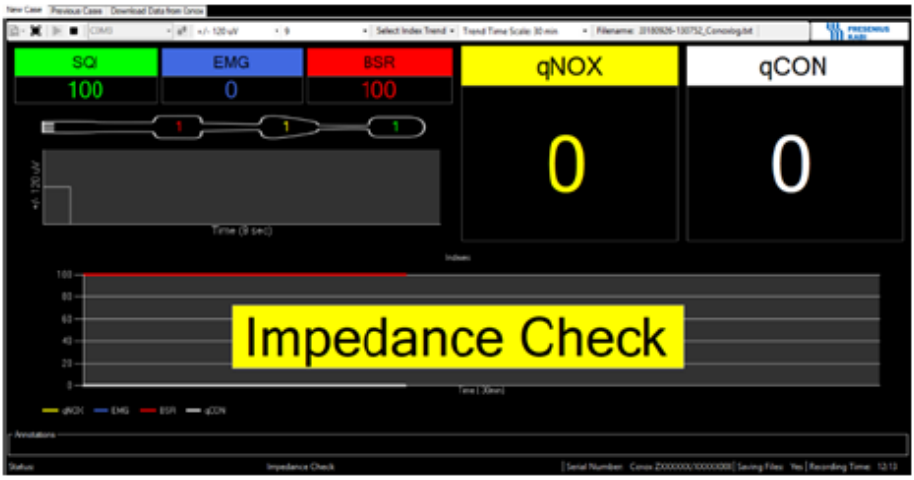
Artefact

Conox has detected an artefact.



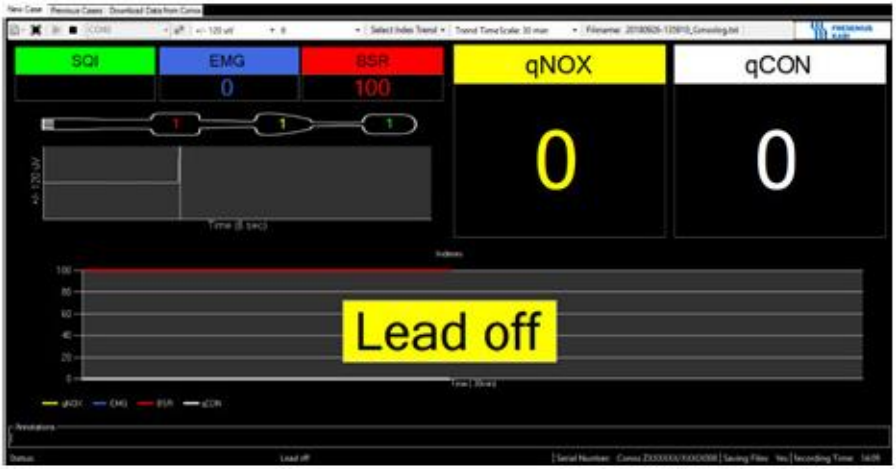
Impedance check

Conox performing an impedance check. During check the impedance readings for each electrode are not displayed



Lead off

Conox has detected a lead off condition.



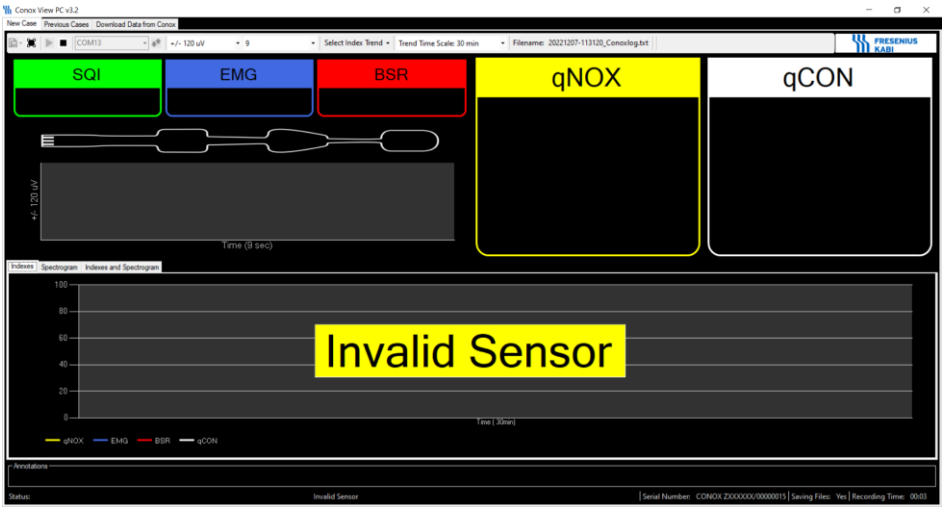
No data received from Conox

Conox is disconnected from the PC.
Ensure the Bluetooth is enabled and PC and Conox are paired.

If ConoxView displays this message, use only Conox for patient monitoring.
In the event data is interrupted, ConoxView will automatically try to reconnect.

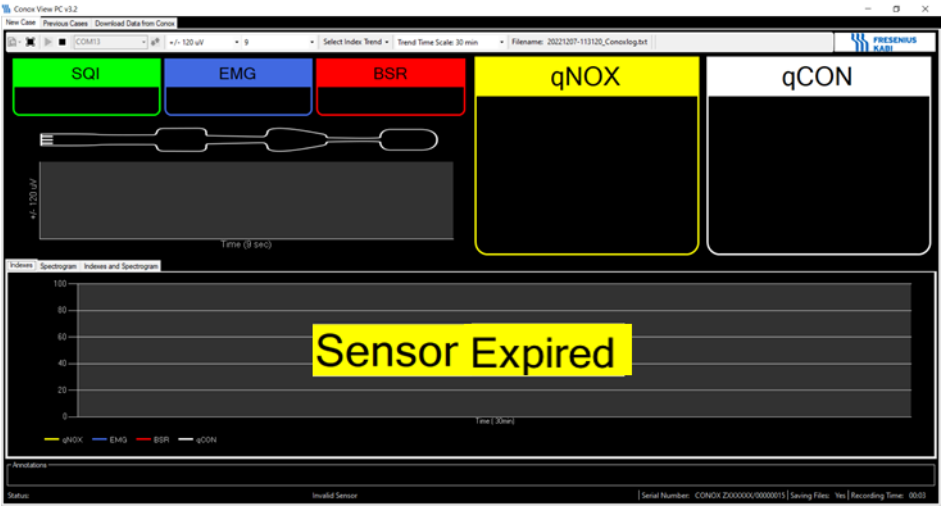
Sensor Invalid

The sensor connected to Conox is not valid (Sensor contains electronic identifier). Replace the actual sensor for a valid one.



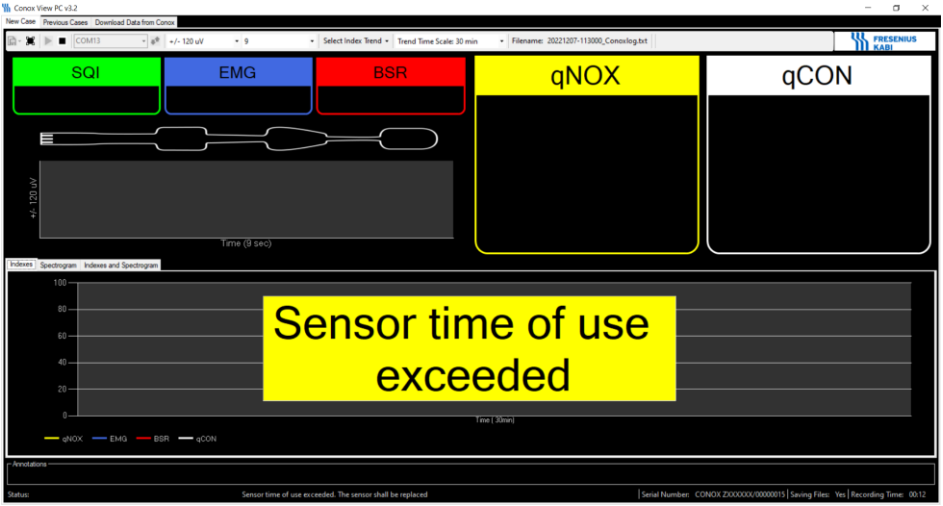
Sensor Expired

The sensor connected to Conox is valid, but it is expired.



Sensor Time of Use Exceeded

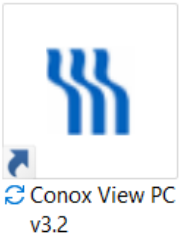
The connected sensor has been used for much longer than 24 hours.



5. Using ConoxView

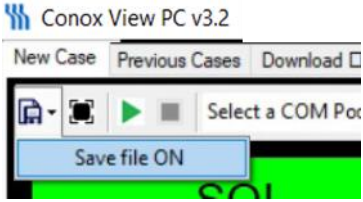
5.1. View and record current Conox case

Click on the ConoxView PC icon in the Desktop.



Select a COM Port in the toolbar of the main screen:

Set "Save file ON" or "Save file OFF" on the toolbar and press "Play".



Press "Stop" to end the view/recording.
When recording, the user can add annotations. Annotation time will be saved automatically with the text.

If ConoxView shows different or inconsistent values from the Conox monitor, the user shall use the Conox monitor values.

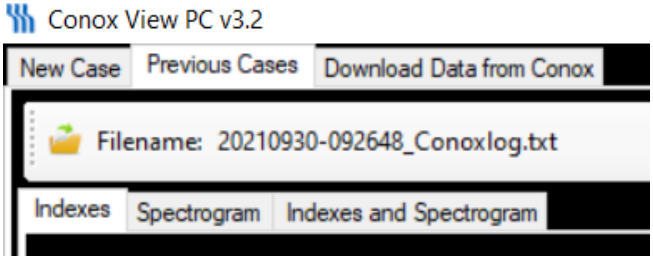
5.2. Replay saved case

Recorded session are stored as a .BIN file in the CONOX_Files folder. These filescontain all the data uploaded by the Conox: raw EEG, qCON, qNOX, EMG, BSR and SQI indexes, serial number, firmware version, impedances values, date time, and device status. The Software also saves the indices,

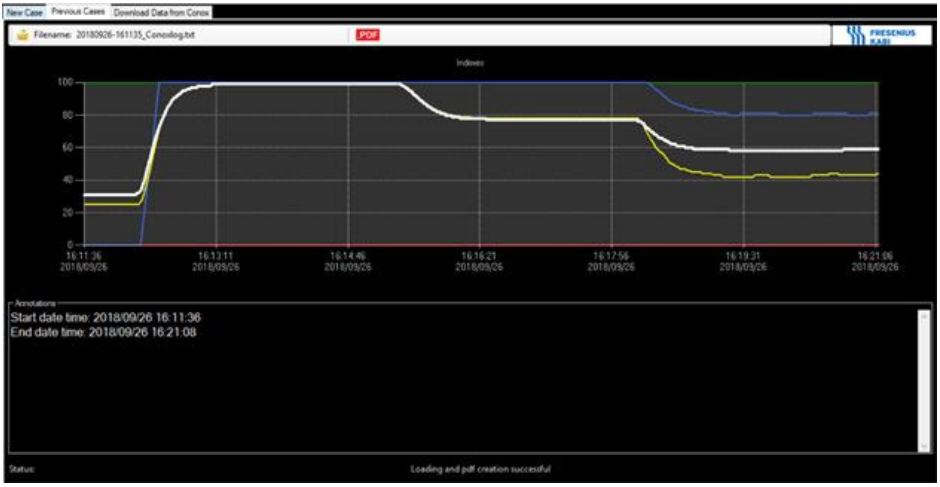
impedance values, device status and annotations introduced by the user in a .txt file.

The name of both files is composed of: date (YYYYMMDD), hyphen, and recording start time. The .BIN file ends with "_Conox_stream" and the .txt file with "_Conoxlog":

To visualize a previous case, press the "Previous cases" tab in the main screen and open the .txt file of the case you wish to display.

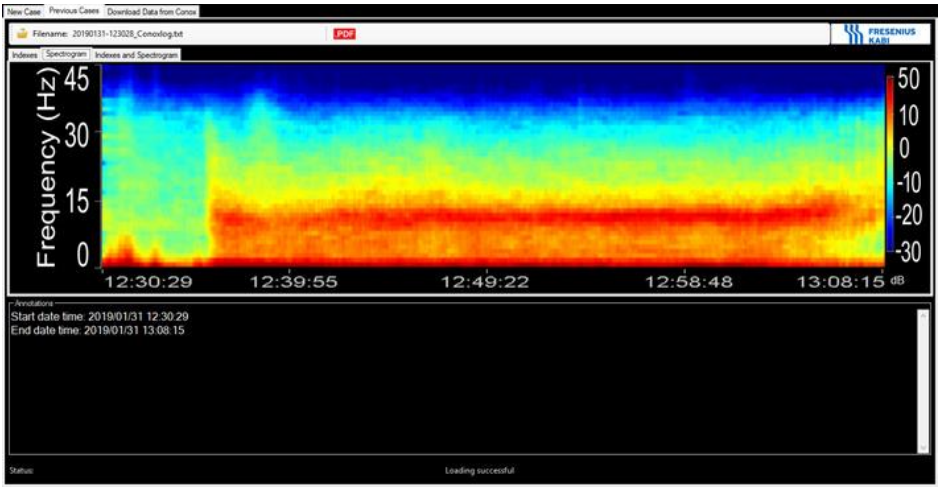


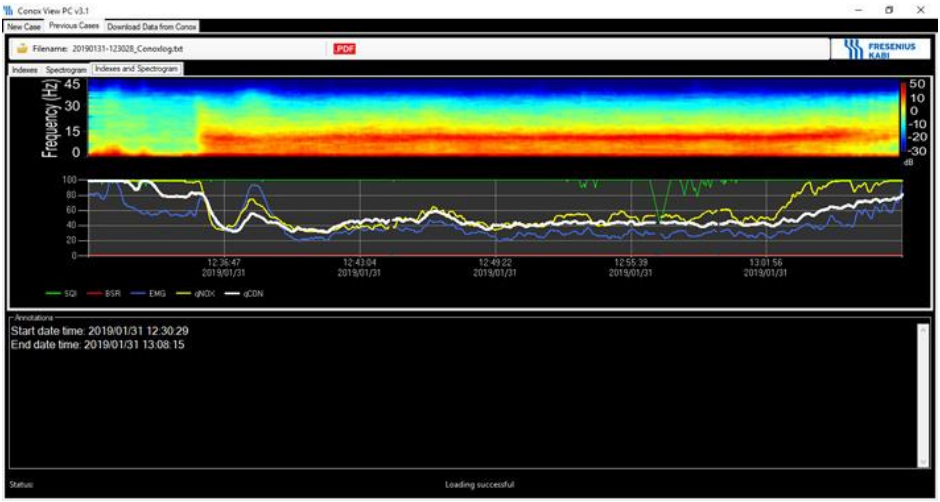
The entire case will be displayed, showing the trends of the four possible parameters and the start/end times.



A PDF file may be created by clicking on the PDF button:

Spectrogram image is also stored on the user PC in the same folder as the ".txt" and ".bin" files. When the ".txt" of a previous case recorded with ConoxView 3.2 is loaded in the "Previous Case" tab, the spectrogram is also shown.





5.3. Download a case

Follow the Conox IFU to transfer a case to the PC.
The downloaded cases will be stored in the CONOX_Files folder.
Download case is only available for Conox with Serial Number of 16 digits (ZXXXXXX/XXXXXXXX).

6. Cybersecurity Considerations

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

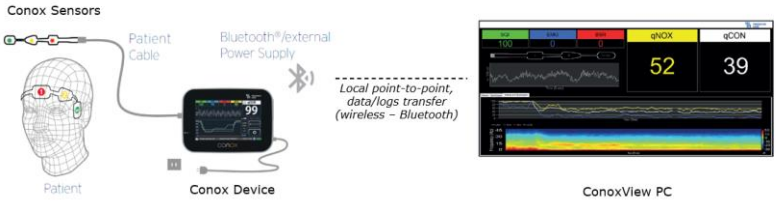


Figure 1 – ConoxView PC diagram

Ensure the application is installed on a trusted device (managed by organization IT department and conform to the IT / Information Security policies applicable within the end-users organization).

Ensure the application is used by authenticated local users, logged in the hosting operating system.

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

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.

Ensure Conox data are properly archived (backup) if required, depending the use related to those data within end-users organization.

Ensure application is installed only from Fresenius Kabi provided installers executables. Check regularly for latest updates of the application from local Fresenius Kabi representative or Key2* platform.

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).

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Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg, GERMANY
Tel.: +49 (0) 6172 / 686-0
www.fresenius-kabi.com

Fresenius Vial S.A.S.
Le Grand Chemin
38590 Brézins - FRANCE

* https://key2.fresenius-kabi.com