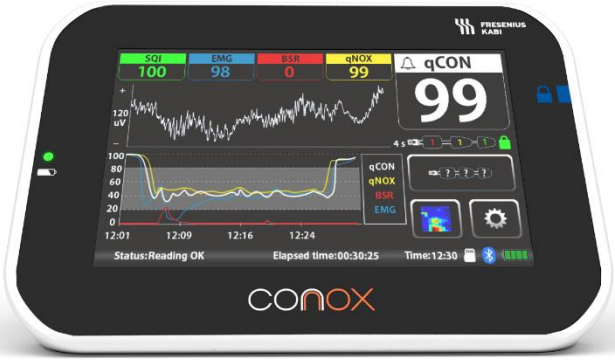
FRESENIUS KABI

caring for life

Conox® 2D

Depth of Anesthesia Monitor

Instructions for Use



Abbreviations

AC	Alternating Current
ADC	Analogue-Digital Converter
CT	Computed Tomography
DC	Direct Current
EEG	Electroencephalogram
EMC	Electromagnetic Compatibility
MRI	Magnetic Resonance Imaging
PCB	Printed Circuit Board
RF	Radio Frequency

Table of Contents

1. General Information

1.1. Scope

These Instructions for Use (IFU) are relevant for the operation of the Conox Depth of Anesthesia monitor (the "Device"). Here you will find how to install, operate and maintain the Device. It is important that you read and understand the manual fully before using the Device.

Ensure that all users of the Device are suitably trained and qualified, and make sure that they have access to this manual.

1.2. Intended purpose

The Conox is intended to monitor patient's consciousness and responsiveness during general anesthesia or sedation.

1.3. Clinical benefits

The Conox monitor allows a trained anesthetist to identify the specific patient state during anesthesia and a correct action following a successful prediction of patient anesthetic state leads to the following clinical benefits:

- Reduced incidence of awareness under anesthesia
- Optimized drug consumption
- Reduced anesthetic exposure
- Attenuation of potential postoperative adverse effects from overdose
- Reduced time needed for post anesthesia recovery and tracheal extubation
- Reduced risk of postoperative delirium and postoperative cognitive disorders
- Reduced ICU stay and hospital stay.

1.4. Indications for use

Conox is intended to be used on patients undergoing general anesthesia or sedation.

Conox is intended to be used by healthcare professionals trained in anesthesia.

Conox is intended to be used in hospitals, medical facilities and road ambulances.

Conox has primary and secondary indexes, each computed from the patient's EEG:

Primary Index:
qCON: A 0-99 dimensionless scale, to serve as a guide to evaluate the patient's level of consciousness.

Secondary Index:
qNOX: A 0-99 dimensionless scale, to serve as a guide to assess the patient's probability of response to noxious stimuli.

1.5. Contraindications

Conox indexes should NOT be used as the only parameters to adjust the dose of anesthetic drugs.

Conox is NOT intended for use in patients with a clinical record of psychiatric/ neurological disease, drug/ alcohol abuse or medication known to affect the central nervous system.

Do NOT use in presence of CT, MRI, X-Ray machine.

Conox is NOT intended to be used during defibrillation.

1.6. Contact address

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

1.7. Symbols

Symbols used in this manual:

Warning: A possible hazard may result in serious personal injury and/or damage to the product if instructions are not followed

1.8. Disclaimer

Manufacturer reserves all rights. No part of this document may be reproduced or published, in any format without written consent of the Manufacturer.

The instructions in this manual are intended for trained professional medical personnel and/or authorized personnel to service and maintain the Device.

All final decisions on patient treatment are the sole responsibility of the healthcare professional in charge and under no circumstances should the Device be used as the sole parameter for adjusting the anesthetic dose.

2. Safety

2.1. General safety instructions

The performance of the Conox device may be affected by the quality of the EEG signal. The quality of the contact between the Conox Sensor and the skin is the primary contributor to electrode-skin impedance. If the patient skin is not prepared as indicated or the sensor is positioned incorrectly, this may lead to artifacts and incorrect monitoring. Artifacts may also arise from physiological sources (muscle activity, eyes motion and blinking) or from external sources, such as surrounding electromagnetic interference. In both cases, the readings of the device might be altered or delayed with respect to the clinical state of the patient.

The readings of the qCON and qNOX indices may be affected by variations in each individual – especially in the pediatric population – the combination of anesthetics administered, and the type of surgical procedure performed. The use of particular anesthetics such as N_2O may also affect performance.

Follow all instructions, recommendations and warnings throughout this manual without exception.

DO NOT open or remove any covers of any of the delivered items due to the danger of electrical shock.
DO NOT use any power supply except the one provided by the Manufacturer.
DO NOT attempt to replace or repair any of the delivered pieces without contacting or informing the Manufacturer.
DO NOT use the Device in the presence of ionizing radiation.
DO NOT use the Device in the presence of a CT scanner.
Do NOT store or use the Main Unit in a location where it is prone to spillages, since liquid entrance can cause device damage.
Do NOT place the Patient Sensor electrodes close to the surgical area, avoid contact of the Patient Cable with conducting wires and ensure that the return plate is in good contact with the patient in case of electrocautery use

STOP using the Device if:

Any cables have damaged insulation.
Any liquid falls onto the Device. If this occurs, switch off the Device, disconnect the cables and follow the cleaning instructions in section 10.
There are any signs of an electrical fault.
There are any signs of mechanical faults or breakage.
There is any mechanical damage or loss of rigidity.

If the Device has been stopped for safety reasons, contact the Manufacturer before any further use.

2.2. Electromagnetic compatibility

The Device is intended to be used in a controlled electromagnetic environment as defined in this manual.

The equipment is in conformity with the standards regarding Electromagnetic Compatibility, not causing electromagnetic disturbances, and complying with immunity standards. To prevent adverse events to the patient and Operator due to electromagnetic disturbances, please refer to section 14.

2.3. Safety symbols

The following signs and symbols are used on the Device and labelling.

	Medical Device		Manufacturer
	Refer to Instructions for Use		Manufacturing date (where XXXX is year manufactured)
	Warning		Bluetooth® communication
	Product reference		Expiry date
	Product serial number		Single use
	AC current		24-hour continuous use
	DC current		Temperature limits

Input terminal connector

Recycle device according to recycling compliance scheme

Latex free

Lot number

Battery symbol

CE Mark and Notified Body Number

Name and address of the manufacturing facility

Do not use if damaged packaging

Nonsterile packaging

Recyclable material

Type BF equipment

Wireless

Unique Device Identifier

(01) Product identifier GTIN
(21) Product serial number
(11) Date of manufacture
(240) Product Reference

2.4. Packaging symbols

The following signs and symbols are used on the Device packaging.

Unique Device Identifier

Fragile, handle with care

This side up

Keep dry

Humidity

Temperature limits

Recyclable material

Recyclable material

Pressure (hPa)

Device with sensor authentication

3. Description

3.1. System description

Conox is a device designed to be used by clinicians during anesthesia and sedation procedures.

A sensor placed on the patient's forehead transmits the EEG signal to the analogue-digital converter (ADC); the ADC amplifies and digitizes this signal. The Device filters the ADC data, rejects artefacts, and processes it using digital signal processing techniques. The EEG signal is processed to extract its complex characteristics to recognize changes of pattern in time.

The EEG represents neural activity that occurs below the upper layers of the brain (cortex). It reflects the compound synaptic activity of excitatory and inhibitory post-synaptic potentials generated by cortical neurons.

Even though clinical decisions should not be taken relying solely on the Conox index values, the Device is a tool to alert clinicians about potential changes in patient's condition.

The Conox is not an EEG diagnosis device and should not be used for EEG monitoring purposes other than anesthesia monitoring.

The use of Ketamine (either as a bolus or a continuous infusion) might provoke a transient increase of qCON and/or qNOX indices that is not linked to the anesthetic state of the patient

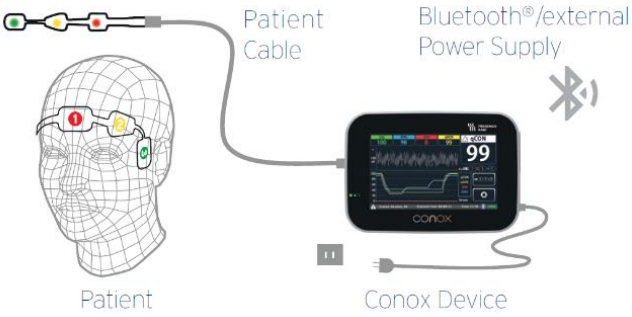
3.2. System overview

The Conox system is a Depth of Anesthesia monitor consisting of:

- Patient Sensor – A disposable, single use array of three Ag/AgCl electrodes.
- Patient Cable – Reusable cable that connects the Patient Sensor to the Main Unit.

- Main Unit – A tablet shaped unit containing PCBs and touch screen display. The unit can be attached to a pole clamp.

- External Power Supply - An external medical grade DC power supply.

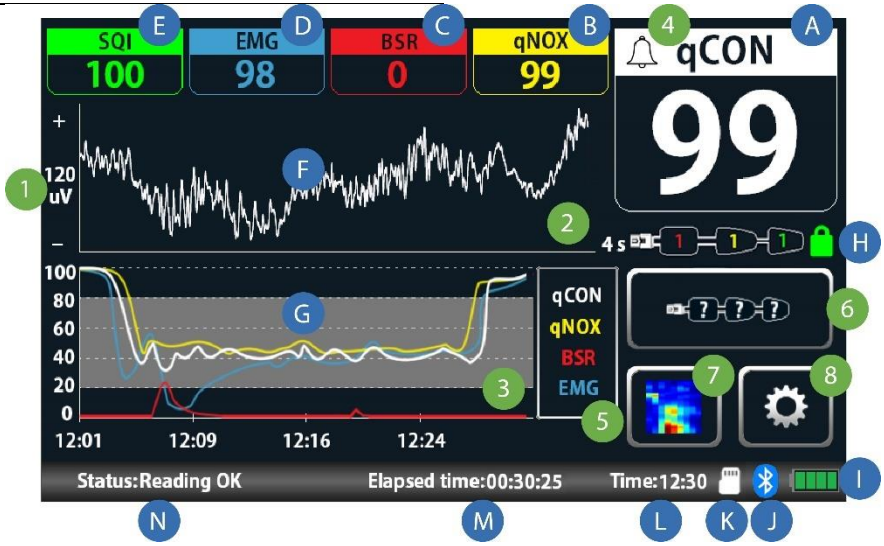


3.3. Controls and indicators

The Device is controlled and interpreted via a touch sensitive screen:

Indicators	
A	qCON index
B	qNOX index
C	Burst Suppression Ratio (BSR)
D	Electromyogram index (EMG)
E	Signal Quality Index (SQI)
F	EEG waveform/Spectrogram
G	Trends graphs
H	Electrode impedance (kΩ) and sensor status
I	Battery status indicator
J	Bluetooth® indicator
K	SD symbol
L	Time
M	Elapsed time
N	Status

Controls	
1	EEG graph amplitude
2	EEG graph timescale
3	Trends graph timescale
4	qCON advisory status
5	Selected parameter trends
6	Manual impedance check button
7	EEG/Spectrogram button
8	Settings button



3.4. qCON index

The qCON index is a continuously processed EEG parameter that correlates with the patient's level of consciousness on a dimensionless scale of 0-99. Decreasing qCON index values correspond to the gradual loss of consciousness and a deepening of the level of anesthesia, so that qCON can be used to track the effects of certain anesthetics on the brain.

The qCON index is exponentially averaged. Each second the displayed index is updated by up to 10% by the newly computed index. Therefore, it is stated that the update time for the device is 1 second and that the response time (the time taken to register a major change of state) is 20 seconds.

The qCON should not be used as the sole parameter for adjusting the anesthetic dose.

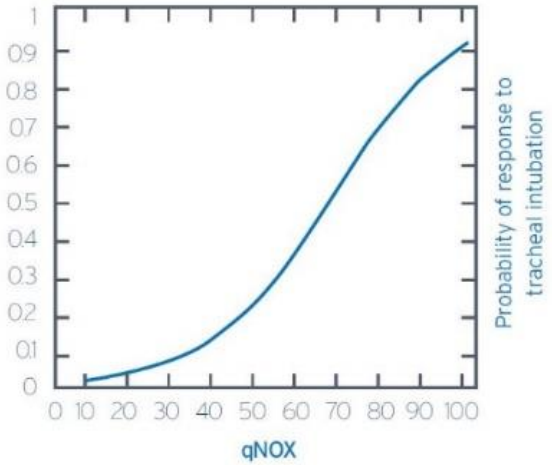
The range of adequate anesthesia is typically represented by a qCON range between 40 and 60. In aware patients qCON will normally be above 80 (this can decrease to 60 in aware patients who are very calm or sedated).

qCON Index Range	Expected Clinical State
80-99	Awake
61-79	Sedation or light anesthesia
40-60	Adequate anesthesia
0-39	Deep anesthesia

3.5. qNOX index

The qNOX index is a continuously processed EEG parameter that corresponds to the probability that a patient responds to noxious stimuli under general anesthesia or sedation, and it is reflected on a dimensionless scale of 0-99.

qNOX Index Range	Expected Clinical State
61-99	Patient likely to respond to noxious stimuli
40-60	Patient unlikely to respond to noxious stimuli
0-39	Very low probability for the patient to respond to noxious stimuli



3.6. Burst Suppression Ratio (BSR)

With a range 0-100%, the Burst-Suppression Ratio (BSR) provides a measure of the percentage of flat EEG observed in a 30 second time frame. This parameter is helpful for detecting deep anesthesia.
When the anesthesia is very deep, a specific pattern called Burst-Suppression is observed in the EEG. In this state, the EEG presents periods of flat signal (suppressed EEG) interrupted by periods with EEG of higher amplitude (bursts).

3.7. Electromyography index (EMG)

The EMG index refers to the facial component of the muscular electrical activity embedded in the EEG recording. The EMG energy (in decibels) is in the frequency range of 30-42 Hz. EMG activity can increase due to:

- Reflex reactions to painful stimuli during surgery.
- Activity or muscular rigidity.

3.8. Signal Quality Index (SQI)

A 0-100 dimensionless scale, it represents the quality of the EEG signal and is calculated based on artefacts.

3.9. EEG waveform

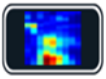
Graphical representation (downsampled) of the EEG waveform.

3.10. 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.

Clinical decisions should not be taken relying solely on the Spectrogram.

The spectrogram and the EEG signal cannot be displayed at the same time. Spectrogram is accessed by pressing the "Spectrogram" button in the main Recording mode screen.



Press the "EEG" button to display the EEG waveform again.

3.11. Parameter trend graphs

qCON, qNOX, BSR and EMG parameters may be selected for graphing. All, some or none of them can be selected.

3.12. Electrode impedance

The Device gives a continuous reading of the impedance (measured in kΩ) between each electrode of the Patient Sensor and the patient's skin. The color of the displayed number corresponds to the color of the numbering on the Patient Sensor.

3.13. Battery status indicator

The charge status of the battery is indicated by bars within the battery symbol.

3.14. Bluetooth® indicator

When the Bluetooth® is ON, a runic B is shown in the lower right side of the display. This B is colored depending on the Bluetooth® status:

Bluetooth® enabled but not transmitting data

Bluetooth® enabled and transmitting data

 Error (See section 12)

If the Bluetooth® is disabled, no icon is displayed.

Bluetooth® is always enabled during Data Repository mode although no icon is displayed.

3.15. SD symbol

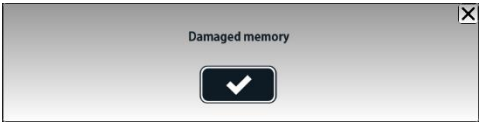
The SD symbol shows correct functioning of the on-board memory. If a red cross is overlaid the symbol, it signifies a memory card error.

 OK

 Micro SD error

Press the symbol to display the name of the file that is currently being recorded.

If the memory is damaged, the following message shall be displayed.



See section 12 for more details.

3.16. Time

Indicates the system time. This may be adjusted in the Settings menu.

3.17. Elapsed time

Indicates the time from when the user switched on the Device or from the last time a new session was created.

3.18. Device Status

The status can display the following messages:

Artefact
The Device has identified an artefact and rejected it.

Status: Artefact

An artefact is a received signal that is not consistent with normal EEG behavior according to the Device algorithms. Artefacts are rejected and not used in calculation of parameters.

Init
This status is shown during initialization when the Device is turned on.

Status: Init

Lead off
The Patient Cable and/or the Patient Sensor or one of its electrodes is disconnected from the Device.

Status: Lead off

The message may also be incorrectly reported where the Device is experiencing very strong EMC interference, for example during electrocautery.

Paused
The download is paused.

Status: Paused

Reading OK
The Device is operating correctly.

Status: Reading OK

Reconnecting...
Failure of internal data transmission. System reconnecting.

Status: Reconnecting...

Deleting files
The Device is erasing the selected file(s).

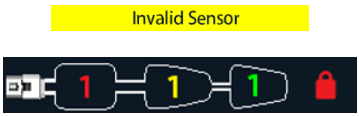
Downloading
The Device is sending the selected file to the PC via Bluetooth®.

Exploring files
Stand by status until the user selects a file.

Impedance test
The impedance of the Patient Sensor is being checked. During this time the Device parameters will not be updated.

3.19. Sensor status

The Patient Sensor status is being checked continuously. During this time different events can happen:

State	Display and Sensor Status	Action
The sensor connected to Conox is not valid (Sensor contains electronic identifier)		Replace the actual sensor for a valid one. If the sensor used is already valid, contact the Manufacturer

The sensor connected to Conox is valid but it is expired	Sensor might be expired. Please check the validity date 	Check the validity date on the sensor package. In case it is expired replace the actual sensor for another one
The connected sensor has reached the 24 hours of use	Sensor time of use exceeded.The sensor shall be replaced 	Replace the actual sensor with a new one
The connected sensor has been used for much longer than 24 hours	Sensor time of use exceeded.The sensor shall be replaced 	Replace the actual sensor for a new one
The sensor is valid and correctly connected to Conox	Status: Reading OK 	-

4. Setup

4.1. Unpacking the Device

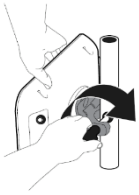
DO NOT open or remove any covers of any of the delivered items due to the danger of electrical shock.
DO NOT use any power source other than that supplied by the Manufacturer.
If any parts delivered show signs of damage, do not use, and contact the Distributor immediately.

4.2. Inside the box

Item	Code
Conox Main Unit	Note: Code is country dependent
Patient Cable	Z185059
Power supply	Z185032
Power cable	Note: Code is country dependent

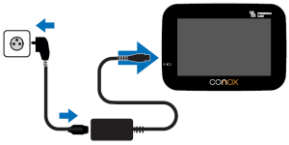
4.3. Installing for the first time

Connect the Main Unit to an IV pole with the pole clamp.

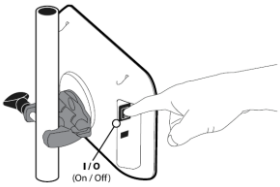


Do NOT use the Main Unit in locations where it is prone to spillages, since liquid entrance can cause device damage

Connect the External Power Supply.



Turn the Device on.



Adjust the settings of the Device. Refer to section 5 for information on how to do this.

The equipment should not be installed next to any bag of liquids being used by the patient.
Also, during cleaning the equipment should not be exposed to spills.

5. Setup menus

5.1. Operating modes

Conox has two operating modes:

a) Recording mode is default at turn on. In this mode the Device automatically starts recording a new case.

b) Data Repository mode allows the user to explore, download, bookmark, review or delete recorded files.

No monitoring can be performed while this mode is enabled.

5.2. Recording mode Settings

Setup menu is accessed by pressing the "Settings" button in the main Recording mode screen.

Settings Selection screen will be displayed.

Press the appropriate icon to change the corresponding setting.

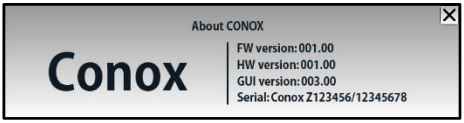
Selections are confirmed by pressing the "Confirm" button.

"Back" button may be used to return to the previously displayed screen.

Configurations selected by the user are saved for next session.

5.2.1. Information screen

Press the "Information" button to see Conox firmware, hardware, software and serial number information.



5.2.2. Language

To change the language, press the "Language" button.

Conox is available in 20 languages:

CES	Czech	NLD	Dutch
DAN	Danish	NOR	Norwegian
DEU	German	POL	Polish
ELL	Greek	POR	Portuguese
ENG	English	RON	Romanian
SPA	Spanish	RUS	Russian
FIN	Finnish	SLK	Slovak
FRA	French	SWE	Swedish
HRV	Croatian	TUR	Turkish
ITA	Italian	ZHO-CN	Chinese

Select one and press “Confirm”:

5.2.3. Time

To set the current time and date, press the “Time” button.

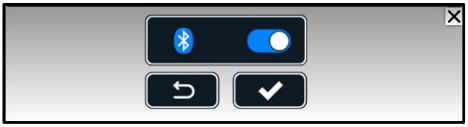
Set date and time and press “Confirm”.

If time is changed while monitoring, data will be saved in a new file.

5.2.4. Bluetooth®

To enable the Bluetooth®, press the “Bluetooth” button in the Setup menu.

Select Bluetooth® “on”



Or select Bluetooth® “off”

When entering the Data Repository mode, Bluetooth® is automatically turned on and the symbol is no longer displayed.

To pair Conox to another device:

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

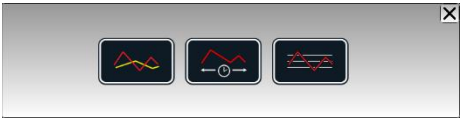
If a password is required, please contact your local distributor to obtain this information.

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

5.2.5. Trends and spectrogram settings

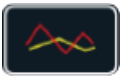
Press "Trends settings" button in the Setup menu to change the graph of the trends.

Trends Settings Selection screen will be displayed.



Trends selection

Desired trends to be plotted may be selected by pressing the "Trends selection" button.



Select the desired parameter/s (all displayed parameters may be selected) and press "Confirm".

Or press directly on the main screen trends legend.

Trends graph and spectrogram timescale

The trends graph and the spectrogram are synchronized in time, so they share the timescale.

Trends graph and spectrogram timescale may be selected by pressing the "Trends graph timescale" button.

Select the trend graph timescale and press "Confirm".

Trends grid

To enable the grid in the trends graph, press the "Trends grid" button.

Select graph grid "on"

Or select graph grid "off".

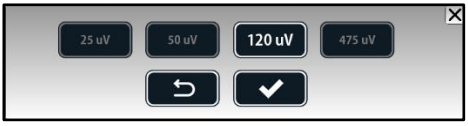
5.2.6. EEG settings

When the spectrogram is displayed on the screen the EEG settings are disabled, so they cannot be adjusted.

EEG graph amplitude

EEG graph amplitude can be set by pressing the "EEG graph amplitude" button.

Select the amplitude and press "Confirm".



Or press directly on the main screen the text label that indicates the current amplitude.

EEG graph timescale

EEG graph timescale may be set from the Setup menu by pressing the "EEG graph timescale" button.

Select the timescale and press "Confirm".

Or press directly on the main screen the text label that indicates the current timescale.

5.2.7. qCON advisory signal

The qCON advisory signal can be enabled by pressing the button below.

The Device is not intended for monitoring only based on the set thresholds.

The advisory will turn ON when qCON is beyond the threshold limits set by the user, followed by display flashes in white and orange changing every second. An audible reminder sounds at 16 second intervals.

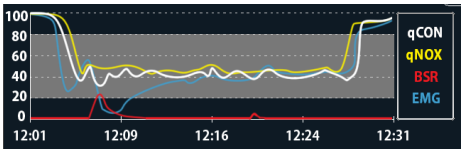
Do NOT use the advisory (acoustic or visual) for unattended parameter monitoring.

The qCON advisory is designed with a sound pressure level between 45dB to 85dB.

Use "+" and "-" buttons or move the horizontal bars to set the limits.

Or to disable select "OFF".

When enabled, the area within the limits is shaded. In the image used as an example below the thresholds are set to 80 and 20.



- Advisory status is indicated in the qCON display box.

On

Off

Upper threshold exceeded (according to example above)

Lower threshold exceeded (according to example above)

Advisory threshold levels are retained from the previous session.

The qCON advisory settings can also be enabled from the qCON display box.

5.2.8. Data Repository

To enter the Data Repository mode and work with recorded cases, press the "Data Repository" button in the Setup menu.

Press the "Confirm" button.

For further information of working in this mode refer to section *7*.

5.2.9. Brightness

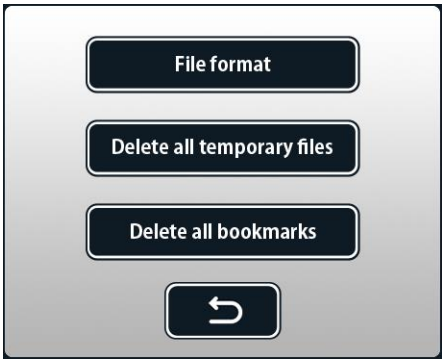
To select the brightness of the display, press the "Brightness" button.

Select brightness level by using "+" and "-" buttons.

5.3. Data repository mode Settings

Enter Data Repository mode and press the "Advanced setup" button.

The following Advanced setup menu will appear:



5.3.1. File format

Press the "File format" button to change the format of the file.

Choose a format and press "Confirm":

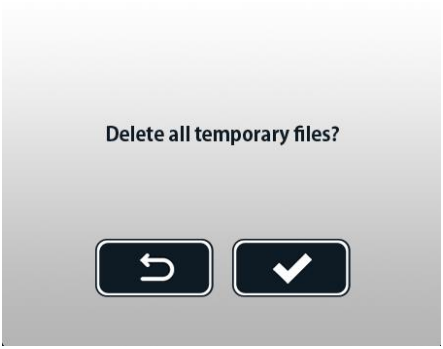
a) Default data: Downsampled and quantized (2 bytes/sample at 128Hz) data set stored taking up less memory and shorter download time.

b) Full data: Full data set (3 bytes/sample at 1024Hz) stored. File sizes are bigger and download times longer.

5.3.2. Delete all temporary files

To delete all the cases stored at the Temporary files folder, press the "Delete all temporary files" button.

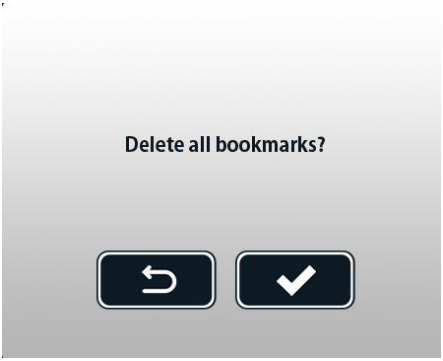
Press "Confirm":



5.3.3. Delete all bookmarks

To delete all the cases stored at the Bookmarks folder, press the "Delete all bookmarks" button.

Press “Confirm”:



6. Recording a new case

To start recording a new case, press on the "Elapsed time" area in the status bar, and press the "Confirm" button.

Conox will automatically start recording a new case in the following situations:

a) Each time the Device is turned on.

b) Each time the user leaves the Data repository mode to return to the Recording mode.

If a case exceeds 6 hours or a user changes the time during a case, a new file record will begin with the filename incremented by +1.

7. Data Repository mode

7.1. Access

Data Repository mode is activated by pressing the "Data Repository" button in the setup menu.

When entering the Data Repository mode, Bluetooth® is automatically enabled and the monitoring of the current case is stopped.

To exit the Data Repository mode, press "Back" and confirm the following message.

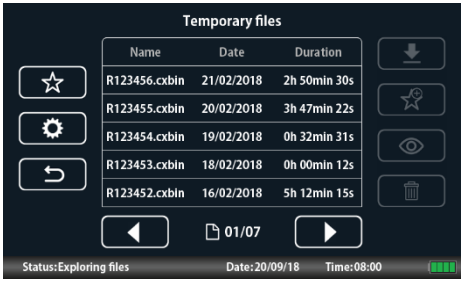
7.2. Folders

Data Repository mode has two accessible folders: Temporary files and Bookmarks. The name of the current folder is written at the top of the user interface.

a) The Temporary files folder saves cases automatically. Once the maximum number of cases (50) has been stored, the oldest case will automatically be deleted.

b) The Bookmarks folder stores the case permanently or until the user deletes it.

By default, Conox records and shows the Temporary files folder:



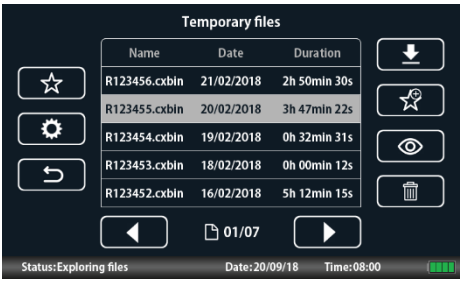
User can access the Bookmarks folder by pressing the "Bookmarks" button.

To access the Temporary files, press the "Temporary files" button.

Each folder can store a maximum of 50 files displayed on several pages. The arrow buttons are used to navigate between screens.

7.3. Recorded cases

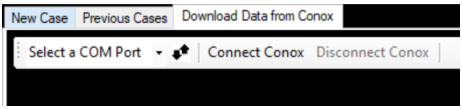
Access a recorded case by pressing on it. The selected case will be highlighted in grey and the right-hand buttons shall be activated.



7.3.1. Download a case

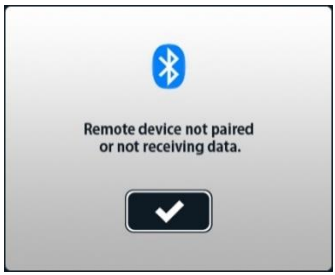
To download a case, ConoxView must be installed on the user's PC and the Conox and PC paired.

In the ConoxView application press the "Download Data from Conox" tab, select the COM Port and press "Connect Conox".

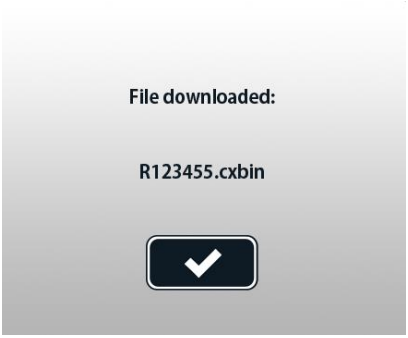


Enter the Data repository mode in Conox, select a case and press "Download".

The following message will appear if the user presses the "Confirm" button but the Conox is not paired:

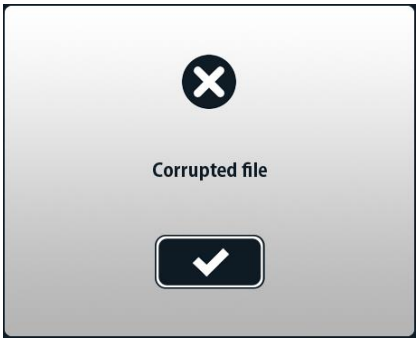


Once the download has finished a notification will be displayed:



And the full case will be shown in the screen of your PC.

If the download is not successful, the following message will appear. See section 12 for corrective actions.



During the download, press "Pause" to temporarily pause the download.

Press "Play" to resume the download.

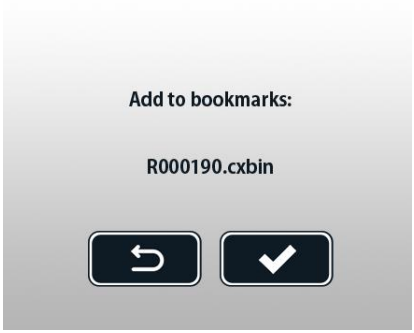
Press “Stop” to terminate the download.

7.3.2. Add a case to bookmarks

The “Add to bookmarks” button is only enabled in the Temporary files folder

Select a case and press the “Add to bookmarks” button.

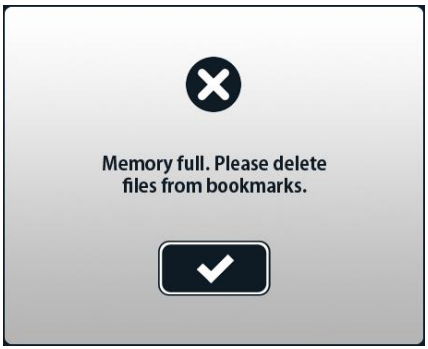
Press “Confirm”.



When a case is bookmarked, it will be moved to the Bookmarks folder (not copied), i.e. it will not be displayed in the Temporary files folder and will be only accessible from the Bookmarks folder.

Once a case is bookmarked, it cannot be moved back to the Temporary files folder.

A maximum of 50 cases may be saved in the Bookmarks folder. If the folder is full the selected case will not be bookmarked and the following message will appear:



Space may be made in memory by deleting previous bookmarked cases.

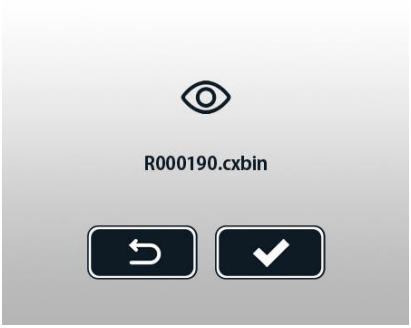
If the file name already exists, the case will not be saved and the following message will appear:

To store the selected case as a bookmark the pre-existing with that name must be deleted.

7.3.3. Review a saved case

To view the trends of a saved case, press on the "Review" button.

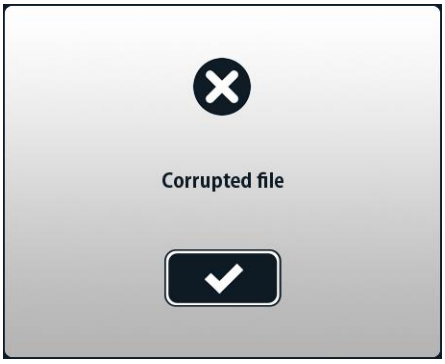
The following message will appear:



The case review will show the trends graph, including EMG, BSR, qNOX and qCON indices of the saved file.

Press the “Back” button to leave the review.

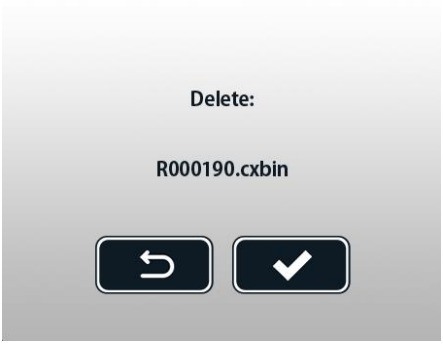
If there is an error Conox will display the following message:



7.3.4. Delete a case

Select a case and press the “Delete” button.

The following message will appear to confirm deletion:



8. Using the device

8.1. Positioning the Device

The equipment should not be used adjacent to or stacked with other equipment. If this is necessary, the user should verify normal operation of the Device in the configuration that will be used.

The Device requires special cautions regarding EMC. It should not be used in the presence of mobile phones and other devices that may cause radio frequency interference.

The Device may be used during electrocautery, but the index values should be interpreted with caution.

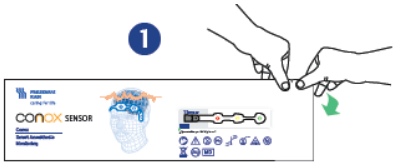
In case the Device is used during long periods of electrocautery, the signal might be lost and index values may not be shown.

The Device may not be used during defibrillation.

Before defibrillation the Patient Sensor must be removed and the Patient Cable disconnected to avoid energy loss through applicable parts and device malfunction or damage.

8.2. Patient sensor

Remove Patient Sensor from packaging.



Do not use the Patient Sensor if it is past the date of expiry indicated on the packaging.

Patient Sensor must not be used for more than 24 hours of continuous use.

The Patient Sensor is a single use device and must be disposed of after use.

Avoid fluids/liquids contacting the Patient Sensor.

Do not re-use sensor if it has been dropped while outside of the pouch.

Resting patients in prone position may cause increased pressure between the skin and the sensor leading to skin irritation.

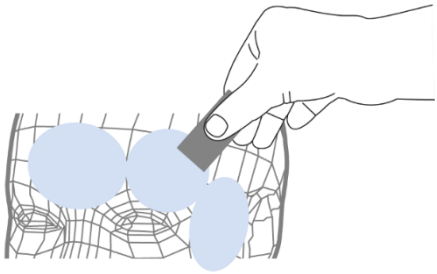
The Patient Sensor must be removed during defibrillation to avoid damage.

In case of usage of the Device during defibrillation, the Patient Sensor electrode sites may produce burns on the patient's forehead.

In case of pediatric patients, the use of the Conox Pediatric Sensor is recommended.

8.3. Skin Prep

Good contact between the Patient Sensor and the patient's skin is required. Before placing the electrodes, carefully clean the patient's forehead skin in the areas indicated using the sandpaper provided in the Patient Sensor packaging.



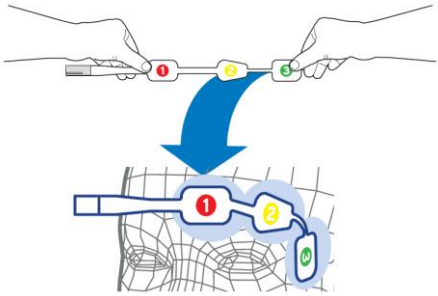
It is important to take special care with patients with skin problems.
Do not use alcohol to clean the skin as this may leave a film which increases the electrode impedance.

8.4. Placement of electrodes

The Conox device is designed to work with Conox Patient Sensors only.

Patient Sensor may be placed either left or right side.

Patient Sensor has color coded pads. Place Patient Sensor on the patient forehead in accordance with the diagram (red: positive active electrode; yellow: reference; green: negative active electrode).



Do not press the center of the electrode. This will squeeze the conductive gel out and complicate good connection.

Do not put the electrodes in contact with conductive parts (incl. earth).

Do not place the electrodes on wounds.

Do not place the electrodes close to the surgical area.

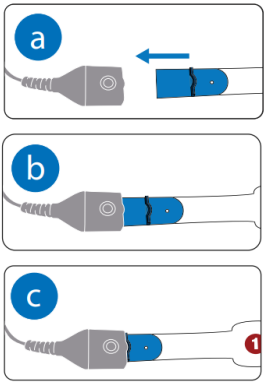
If the skin shows any rash or other unusual symptoms, remove the electrodes from the patient.

If the adhesion or the contact of any of the electrodes is not enough after pressing around the Patient Sensor, use adhesive tape to press/stick the electrode to the skin.

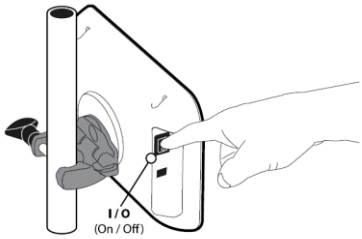
8.5. Connect patient cable & turn on

Connect the Patient Cable to the Main Unit.

Connect the Patient Cable to the Patient Sensor.



Turn the Device on.



8.6. Impedance check

The Device automatically checks the impedance of the Patient Sensor connections when it is turned on and every 15 minutes when in operation.

Impedances below 10 kΩ are considered to be good, being the lower, the better. The impedance in kΩ will be displayed within the Impedance icon on the display.

If the impedance is greater than 10 kΩ the display will show "TH" in a yellow Impedance icon and no computed values will be displayed. The impedance must be below this limit for the Device to work correctly.

If the impedance is "TH" an impedance test is repeated automatically every 10 s until the impedances are below 10 kΩ.

Impedance may be checked on demand by pushing the "Impedance" button.

The Device does not gather EEG or calculate parameters data during impedance checks.

8.7. Event sequence / operation

When the Device is turned on it will measure the impedance of the electrodes (approx. 5s) and then the sensor validity. The EEG trace will be displayed after. Simultaneously qCON, qNOX, EMG, BSR and SQI values will be displayed and the selected qCON, qNOX, BSR and EMG trends will then be displayed.

The Device is now ready to use.

8.8. Patient cable disconnected

If the Patient Cable or Patient Sensor becomes disconnected, the message "lead off" will appear on the screen. Reconnect it as soon as possible.

The Patient Cable must be disconnected in case of defibrillation to avoid its damage and Device malfunction or damage.

9. External power supply & battery

9.1. External power supply

The Conox is supplied with an external power supply.

Model	ME10A0503F01
Rated Input	100-240 Vac 50-60Hz 0.5A
Volts	5.0 V
Output current	2.0 A
Output power	10 W

The Device must only be connected to a mains electrical supply with a protective earth.

Only the external power supply provided by Fresenius Kabi may be used.

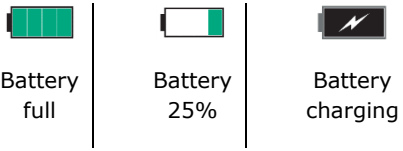
The Device is electrically isolated from the mains supply.

9.2. Battery

The Device has an internal lithium-ion rechargeable battery. The battery will give the device approximately 1.5 hours usage when disconnected from the external power supply. From discharged, the battery will take approximately 10 hours to fully recharge.

The front panel of the Device contains a charge indication LED. When the LED is blue, this indicates that the Device is being powered by main electricity and the battery is charging.

The battery symbol indicates the state of charge:



Battery full	Battery 25%	Battery charging

A battery symbol and the text “Recharge battery” will be displayed when the battery level is low.

The battery must only be changed by technical personnel approved by Fresenius Kabi.

10. Cleaning and disinfection

10.1. Service policy and rules

Do not use cleaning or disinfection agents that contain the following substances as these aggressive agents may damage the plastic parts of the Device and cause the Device to malfunction:

- Trichloroethylene
- Abrasive detergents

10.2. Cleaning precautions

The Device and patient cable should be cleaned as soon as they become contaminated.

After cleaning, the Device should be left to dry for approximately 5 minutes before being started or reconnected to the mains.

The device and patient cable must be cleaned after each patient usage by a trained nurse or nurse assistant.

The Device and its accessories are not intended to be sterilized, it may damage them. The Conox is a non-sterile medical device.

If spray disinfectant is used, it should be applied at least 30cm from the Device.

10.3. Recommended cleaning and disinfection agents

Didecyldimethylammonium chloride (example:Wip'Anios Excel by Anios).

Please contact the appropriate service responsible for cleaning and disinfection products in your establishment for further details.

10.4. Cleaning and disinfection guidelines and protocol

Do not immerse device in liquids or let liquids enter device's housing.

The Device and patient cable are resistant to recommended agents.

10.5. Cleaning instructions

Prerequisites

- The device is switched off and disconnected from the power supply.
- The patient cable is disconnected from the Device and Conox Sensor.
- The air is at room temperature (20 to 25°C).
- The operator is wearing suitable protective equipment.

Protocol

1. Place the device and patient cable on a cleaned surface or disposable underlay.

2. Use a ready-to-use wipe to remove any grime.

3. Thoroughly wipe down all exposed surfaces (housing, display, screw area, pole clamp, switch, connection area, etc.) of the Device. Gently wipe down the Device.

A minimum cleaning of 1 minute is recommended (allow to remain visibly wet for 1 minute), until all organic matter is dissolved and removed.

Do not allow liquids to run, leak, or drip into the Device housing.

4. Repeat step 3 with the patient cable (cable and connectors on both ends).

5. Using a fresh ready-to-use-wipe, thoroughly wipe down all exposed surfaces.

A minimum cleaning of 1 minute is recommended (allow to remain visibly wet for 1 minute), until all organic matter is dissolved and removed.

6. Wipe down the power cord.

7. Allow the device to dry completely at room temperature.

10.6. Disinfection instructions

Prerequisites

- The cleaning protocol has been performed.
- The Device is switched off.
- The power cord and all other cables are unplugged.
- The air is at room temperature (20 to 25°C).
- The operator is wearing suitable protective equipment

Protocol

1. Place the previously cleaned Device and patient cable on a cleaned surface or disposable underlay.

2. Use a ready-to-use wipe to wipe down all exposed surfaces of the Device and patient cable (as described in the cleaning protocol), making sure to cover all cracks, crevices, and hard-to-reach areas.

Do not allow liquids to run, leak, or drip into the Device housing.

3. Using a fresh ready-to-use wipe, repeat step 2. Ensure that the minimum contact time for each step is 3 minutes for bactericide activity (surface remain visibly wet for 3 minutes). Respect the indicated contact time from the manufacturer recommendations for the required antimicrobial activity.

4. Wipe down the power cord.

5. Allow the Device to dry completely at room temperature.

11. Adverse effects

Patient Sensor may cause skin wounds due to allergy, irritability, or other kind of skin problems.

If an artefact adversely affects the signal quality and decreases it, the qCON index and all other parameters will not be displayed.

In case any adverse event is detected, Manufacturer and legal authorities shall be informed.

12. Troubleshooting and Diagnostics

12.1. Conox Alarms

All alarm conditions are classified as low priority based on the IEC 60601-1-8 standard.

Alarm message	Possible causes	Corrective actions
Recharge battery 	The battery level is low.	Connect the power supply to Conox to continue operation and to recharge the battery.
Reconnecting… **Status: Reconnecting…**	An ESD to the system has caused a temporary disconnection between the display and PCB	Display will automatically try to reconnect to PCB. If reconnect does not occur in <10s device will reset.
	An ESD to the system has caused permanent disconnection between the display and PCB	Display will keep resetting since no reconnection is possible. Contact your distributor.
Lead off **Status: Lead off**	Disconnected Patient Sensor	Connect Patient Sensor
	Poor or contaminated connection	Clean connection between Patient Sensor and Patient Cable
	Disconnected Patient Cable	Connect Patient Cable
	Defective Patient Cable	Replace Patient Cable
	Defective Patient Sensor	Replace Patient Sensor
	Defective Device	Contact your Distributor

Invalid Sensor 	The sensor connected to Conox is not valid (Sensor contains electronic identifier)	Replace the actual sensor for a valid one. If the sensor used is already valid, contact the Manufacturer
Sensor time of use exceeded. The sensor shall be replaced. 	The connected sensor has been used for much longer than 24 hours	Replace the actual sensor for a new one
Sensor might be expired. Please check the validity date 	The sensor connected to Conox is valid but it is expired	Check the validity date on the sensor package. In case it is expired replace the actual sensor for another one
Impedance Too High (TH) 	Patient Sensor is not in full contact with patient skin	Press Patient Sensor firmly on to skin (DO NOT press the center of the electrode).
	Defective Patient Sensor	Replace Patient Sensor
	Defective Device	Contact your Distributor
Artefact - Excessive artefacts detected The SQI is <50 **Status: Artefact**	Artefact caused by patient eye blinking or movement. Data unavailable due to poor signal quality If the SQI is too low to accurately calculate a qCON index, the qCON value and other trend variables that are adversely affected are not displayed	Try to minimize patient blinking / movement.
	Happens during electrocautery	The Device is not designed to work during

		electrocautery. It should resume normal operation after electrocautery is complete.
	EMG index indicates electrical activity may be interfering with EEG	The Device may be affected by EMC from other devices such as warming blankets. See section 14 for more information.
	Defective Patient Sensor	Replace Patient Sensor
	Defective Device	Contact your Distributor
Sensor time of use exceeded. The sensor shall be replaced. 	The connected sensor has reached the 24 hours of use	Replace the actual sensor with a new one

The priority among the alarms is:

> Recharge Battery > Reconnecting > Lead off > Invalid Sensor > Sensor time of use exceeded (Hard Limit) > Sensor time of use exceeded (Soft Limit) and Artefact or Too high impedance > Sensor Expired and Artefact or Too high impedance

The artefact alarm can occur only during EEG and index processing while too high impedance can occur only after an impedance check. Hence, these two alarms cannot coexist.

Sensor expired and artefact visual alarm can occur simultaneously, in this case the alarms blink consecutively for 4 seconds during a period of 8 seconds.

Sensor Time of use exceeded (Soft Limit) and artefact visual alarm can occur simultaneously, in this case each alarm blinks consecutively, for half the period, in the status bar with a period of 16 seconds. The period decreases to 8 seconds as use of the sensor continues until the Sensor Time of use exceeded (Hard Limit) alarm.

12.2. Troubleshooting & Diagnostics

Device status	Possible causes	Corrective actions
Operating on backup battery	The Device is running from battery	If unintentional: - Connect external power supply - Replace external power supply cable - Replace external power supply - Defective Device, contact your Distributor
Display goes black	Backup battery is totally discharged	Connect external power supply
	Defective Device	Contact your Distributor
Date and time have not changed	Defective Device	Contact your Distributor
Display Micro SD not mounted	The internal micro SD of the display has become corrupted	Contact your Distributor
Micro SD error/Damaged memory	If the Device displays this message the internal micro SD card has been corrupted	Contact your Distributor
Corrupted file	The file has become corrupted and cannot be retrieved.	Delete file. If this happens repeatedly, contact your Distributor.
Bluetooth error	Error in the Bluetooth module	Contact your Distributor

13. Service

13.1. Warranty

Manufacturer warrants that the Device is free from defects in material and workmanship under normal use of medical personnel and service for a period of 12 months from the date of delivery.

Manufacturer warrants that accessories are free from defects in material and workmanship under normal use of medical personnel and service for a period of 30 days from the date of delivery.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the Distributor. Repair or replacement will be carried out, subject to the terms of this warranty. Any warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner of the Device.

13.2. Maintenance requirements

For service, please contact your Distributor.

A preventive maintenance at least once every **3 years** is recommended, this includes battery replacement.

If the Device is dropped and damaged, please contact your Distributor immediately.

Preventive maintenance must be performed by qualified and trained technical personnel in compliance with the technical manual and procedures.

When replacing components, only use Fresenius Kabi parts.

When using the device on the patient, no maintenance action must be performed.

Life cycle of the Device: 5 years provided that the maintenance is properly performed as described above.

13.3. Service policy and rules

For further information concerning device servicing or use, please contact your Distributor immediately.

Before returning a Device for service please carry out the following:

- Carefully describe the nature of the problem.
- Clean the Device before shipment.
- Use only original packaging for shipment.
- Include all accessories used when the problem occurred.
- Contact your Distributor before shipment to obtain the return procedure.

13.4. Recycling and safe disposal

Before disposal, remove battery from the device. Batteries and devices with this label must not be disposed of with the general waste. They must be collected separately and disposed of according to local regulations. Do not dispose of Conox Sensor in general waste.

For further information regarding waste processing regulations and dismantling, contact your local Fresenius Kabi sales representative.

13.5. Notification of serious incident

Any serious incident that has occurred in relation to the Device should be reported to the manufacturer and the competent authority.

Contact information of the manufacturer:

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

14. Electromagnetic immunity

The Conox system is intended for use in the electromagnetic environment specified below. The user of the Conox must assure that it is used in an environment that meets these requirements.

This section provides the appropriate specification tables for the Device as per IEC 60601-1-2.

Emission Test	Compliance Obtained by the Device	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Conox only uses RF energy for its internal operation. Its RF emissions are therefore very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Compliant (Class A)	The Conox is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Compliant (Class A)	
Voltage fluctuations Flicker emissions IEC 61000-3-3	Compliant	

Immunity test	IEC 60601-1-2	Compliance Level Obtained by the Device	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact	± 8 kV contact	The Device uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	± 2, 4, 8, 15 kV air	± 2, 4, 8, 15 kV air	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Electrical mains power quality should be that of a typical healthcare facilty environment.
	± 1 kV for input/output lines	± 1 kV for input/output lines	
Surge IEC 61000-4-5	± 1 kV differential mode	± 1 kV differential mode	Electrical mains power quality should be that of a typical healthcare facilty environment.

	± 2 kV common mode	± 2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle.	< 5% UT (> 95% dip in UT) for 0.5 cycle.	Electrical mains power quality should be that of a typical hospital environment. For short and long interruptions (< than battery life) of AC power, the internal battery provides continuity of service.
	< 5% UT (> 95% dip in UT) for 1 cycle.	< 5% UT (> 95% dip in UT) for 1 cycle.	
	70% UT (30% dip in UT) for 25 cycles (50 Hz)	70% UT (30% dip in UT) for 25 cycles (50 Hz)	
	70% UT (30% dip in UT) for 30 cycles (60 Hz)	70% UT (30% dip in UT) for 30 cycles (60 Hz)	
	< 5% UT (> 95% interruption in UT) for 200 cycles (50 Hz)	< 5% UT (> 95% interruption in UT) for 200 cycles (50 Hz)	
	< 5% UT (> 95% interruption in UT) for 300 cycles (60 Hz)	< 5% UT (> 95% interruption in UT) for 300 cycles (60 Hz)	
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Conox system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 0.35 \sqrt{P}$ $d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2,5 GHz Where "P" is the maximum output power rating of the transmitter in watts according to the transmitter Manufacturer and "d" is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 1 GHz (Laboratory limitation)	

Notes:
At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Device is used exceeds the applicable RF compliance level above, the Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may by be necessary, such as reorienting or relocating the Device.

2. Over the frequency ranges from 150 kHz to 80 MHz field strength should be less than 3 V/m.

14.1. Recommended separation distances between portable and mobile RF communications equipment

The Device is intended to be used in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the Device can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of Equipment (W)	Separation distance according to frequency of Transmitter (m)		
	150 kHz to 80 MHz d =0.35 √P	80 MHz to 800 MHz d =0.35√P	800 MHz to 1 GHz d=0.7√P
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.1	1.1	2.2
100	3.5	3.5	7

15. System and environment specifications

15.1. Essential Performance

The Device shall:

- acquire EEG signals from the sensors (through the patient cable) in compliance with IEC 60601-2-26
- compute the qCON index
- compute the qNOX index
- compute an index to quantify the quality of the signals being received from the patient (SQI).
- indicate if there is no patient connection (lead off)
- indicate if the patient / sensor impedance is very high and unacceptable for reliable measurement
- Indicate the existence of any artefact that compromises the calculation of the indices.

15.2. System specifications

Monitor main characteristics	
Dimensions	215x150x65mm
Weight	785gr.
Display size	7” (154.08x85.92mm)
Battery	3.7 V Li-ion, 3500mAh, rechargeable
Bluetooth®	5.0, selectable, send only, range up to 8m
Patient Cable length	3m

Indices performance	
qCON index range	0-99
qNOX index range	0-99
EMG index range	0-100
SQI index range	0-100
BSR index range	0-100

Indices update rate	1s
qCON advisory signal	Selectable, high & low limit, audio and visual
Total index update time	20 s
Indices trend graphing	Selectable, qCON, qNOX, EMG, BSR
Lead off detection	Continuous
Sensor impedance check	Automatic every 15mins, on request via panel button

Technical specifications – EEG acquisition	
EEG resolution	44.58 nV
Input Noise	≤ 2.9 µV peak to valley
CMRR	≥ 89 dB
Sampling Frequency	1024 Hz
Input range	± 374 mV
Resolution	24 bit ADC

Technical specifications – EEG processing	
Frequency range (-3dB)	0 – 69 Hz
Filtering	Notch filter (fixed, 50/100/150/200 or 60/120/180/210 Hz, depending on mains frequency for the specific code; see 4.2)

Technical specifications – EEG display	
Frequency range (-3dB)	0.32 – 88 Hz (for 2 second time scale window)
Filtering	(fixed, 50/100/150/200 or 60/120/180/210 Hz, depending on mains frequency for the specific code; see 4.2)

Bluetooth Specifications	
Operating frequency range	2402 – 2480 MHz
Maximum data rate	1 Mbps UART Baud Rate: BR/EDR: up to 32 Kbytes/s LE: up to 7 Kbytes/s
	115200 bps UART Baud Rate LE: BR/EDR: up to 10 Kbytes/s LE: up to 6 Kbytes/s
RX Sensitivity	-90 dBm (BR/EDR), -92 dBm (LE)
Output Power	Class 2 (+ 1.5 dBm typical)
Transmission power	BDR/EDR -6 to +4 dBm
	LE -20 to +10 dBm
Bluetooth version	Bluetooth® 5.0 Dual Mode

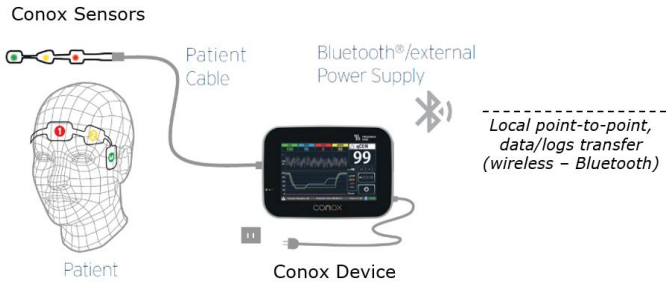
15.3. Operation & shipment environment conditions

Environment - Operation	
Temperature	5 – 40°C / 41 – 104°F
Relative Humidity (non-condensing)	30 – 80 %
Air Pressure	500 – 1060 hPa
Environment – Transport & storage	
Temperature	(-10) – 60°C / 14 – 140°F
Relative Humidity (non-condensing)	10 – 90%
Air Pressure	500 – 1060 hPa

The device shall be operated and stored at the conditions specified in the tables. If these conditions are followed, the device shall not require any waiting period to be powered on and begin operation.

16. Cybersecurity recommendations

The Conox device has been designed to allow the mitigation of commonly known cybersecurity threats targeting network and local point-to-point Bluetooth communication interfaces



To further protect the CONOX device against unauthorized access and its removal from the premises, you must ensure:

- Your premises are secured
- When not in use, the Conox is securely stored
- Secure storage access is restricted to authorized personnel only

Please follow recommendations from 14.1 "Recommended separation distances between portable and mobile RF communications equipment".

Refer to the Conox Technical Manual for more information regarding general cybersecurity recommendations, device cybersecurity features, detailed description of potential risks and compensation controls, and practical cybersecurity guidelines for installation / operations / disposal of the devices.

Medical devices must be deployed within a secure network perimeter to prevent access from unauthorized external system(s).

Should you have concerns with connectivity to the CONOX device, contact your biomedical department or your Fresenius Kabi representative.

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

17. Declaration of conformity

The Device has passed the Immunity to emission of active RF surgical equipment test according to IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 and IEC 60601-2-26.

The Device has been produced in compliance with the Medical Device Regulation (EU) 2017/745, through the application of the following harmonized standards:

UNE-EN 60601-1:2008 + ERR: 2008 + CORR: 2010 + A11:2012 (EN 60601-1:2006 + CORR: 2010 + A11:2011 + A1:2013 + AC: 2014 + A12:2014 / IEC 60601-1:2005 + CORR: 2006 + CORR2:2008 + A1:2012)

UNE-EN IEC 60601-2-26:2012

EN 60601-1-6:2010 (IEC 60601-1-6:2010) AND UNE-EN 62366:2009 (EN62366:2008 / IEC 62366:2007)

EN 60601-1-2:2015 (EC 60601-1-2:2014)

The Device is classified as IIa active device (Rule 10 and Rule 11).

This document may contain inaccuracies or typographical errors. Modifications may thus be done and included in later editions. Due to the evolution of standards, and of legal texts and materials, the characteristics indicated in the text and images of this document are applicable only to the device with which it is included.

Made in France
Revision date: **AUGUST 2022**
Reference: 17783-1 IFU_CONOX_QM7000M_ENG_2D

http://www.fresenius-kabi.com

CE 0123

Local Contacts for Servicing

17783-1_ifu_conox_ENG

FRESENIUS KABI
caring for life

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