DIGITAL CAPNOGRAPH
USER MANUAL

ACCUCAP 911®

Digital Capnograph

PARSIAN MEDICAL Co.

Content

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	Device: **Capnography** Model: **ACCUCAP911** Class: **IIb** Basic UDI-DI: **62618435ACCUCAP911FM** REF **25.01**

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Introduction

A capnograph is a device used to monitor the partial pressure of carbon dioxide in respiratory gases noninvasively. This device is usually used during anesthesia and intensive care procedures. A capnograph usually displays the amount of exhaled carbon dioxide as a waveform per unit of time. This waveform also shows the amount of carbon dioxide in the inspiratory phase, which is especially important when using breathing apparatus (ventilators).

A capnography is a direct method for monitoring the amount of carbon dioxide in inhalation and exhalation and indirectly for measuring the partial pressure of carbon dioxide in arterial blood. In healthy people, the difference in partial pressure of carbon dioxide between arterial blood and exhaled gas is very small, and in children it is almost zero. However, in the presence of pulmonary diseases or certain forms of congenital heart disease, this difference can increase and may exceed 1 kPa (10 mbar).

During anesthesia, critical interactions occur between two primary components: the patient and the anesthesia machine, which typically includes the respiratory circuit and ventilator. The essential connection between these components is through the endotracheal tube and mask, where carbon dioxide levels are monitored. the capnograph provides a direct representation of carbon dioxide exchange from the lungs to the anesthesia machine and an indirectly representation of tissue carbon dioxide production and its transfer to the lungs.

When the volume of exhaled carbon dioxide is equal to the exhaled volume over time, the area under the curve on the capnograph represents the volume of carbon dioxide in each breath. By measuring the carbon dioxide that is send out of lungs per minute, this method provides a valuable metric for assessing metabolic rate. Sudden changes in exhaled carbon dioxide during heart or lung surgery often indicate significant alterations in cardiopulmonary function.

The capnography primarily operates based on the principles of carbon dioxide absorption spectroscopy in the infrared (IR) range. An infrared light beam passes through the gas sample and into the sensor. The presence of carbon dioxide absorbs a

portion of this light, leading to a reduction in the voltage in the sensor circuit. This method is highly accurate and fast; however, the presence of nitrogen oxide gas can affect the results by changing the amount of infrared absorption. To mitigate this error, special techniques are employed, which are automatically adjusted in new generations of capnographs.

Indication for use:

The capnography provides comprehensive information on carbon dioxide production, pulmonary perfusion, alveolar ventilation, respiratory patterns, and the removal of carbon dioxide from the respiratory circuit of the anesthesia machine and ventilator. The shape of the capnography curve can be influenced by certain lung diseases. In general, conditions such as bronchitis, emphysema and asthma are associated with specific changes in this curve. However, conditions such as pulmonary embolism and congenital heart disease, which affect pulmonary saturation, typically do not change the shape of the capnography curve. instead, they do affect the relationship between expiratory carbon dioxide and arterial carbon dioxide levels. Additionally, capnography can measure carbon dioxide production as an index of metabolism. For instance, conditions such as fever and chills can lead to increased carbon dioxide production, while anesthesia and hypothermia may cause a decrease.

Capnography plays a significant role in the early diagnosis of respiratory issues, such as hypoventilation, wrong intubation in the pharynx, and interruption of the respiratory circuit, compared to clinical diagnosis methods. This leads to a significant reduction in the risk of potential injuries to the patient. During sedation, capnography provides more detailed information about the frequency and pattern of breathing compared to pulse oximeter.

simultaneously combining capnography and pulse oximetry can reduce anesthesia-related adverse events up to 93%. This finding, from research conducted by the American Society of Anesthesiology (ASA), underscores the importance of the using these two technologies together to enhance patient safety during anesthesia.

Primary requirements:

- Monitoring vital signs
- Assessing patients for respiratory issues, including apnea, asthma, chronic obstructive pulmonary disease (COPD) through $EtCO_2$ measurement.
- Ventilator management and adjustments.
- Monitoring of intubated and non-intubated patients.

Secondary requirements:

- Monitoring of $EtCO_2$ and $FiCO_2$.
- Monitoring of respiration rate (RR).
- Elimination of interference from other anesthetic gases.
- CO_2 concentration waveform display.
- Visual and audible alarms with high and medium priorities.
- Adjustable alarms with different priorities.
- Trend analysis option for each patient.
- Configurable patient profile settings for adult, pediatric, and neonate.
- Use of electricity and rechargeable battery with capacity of 5 hours with the ability to increase based on the user's needs.
- 7.8'' wide screen with display resolution for a distance of up to 4 meters with adjustable backlight.
- Durable body according to IEC 60601-1 standard for portable devices.
- Complying all requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, ISO 80601-2-55, and IEC 62304 standards.

Additional specifications:

- The option to choose between two different sensors, Microstream and Mainstream.
- Possibility of portable use.
- Potential for placement on a trolley, infant incubator, serum holder and wall-mounted.
- Potential for connecting to Integrated Clinical Environment (ICE) using Ethernet networks supporting TCP and MLLP protocols in compliance with the HL7 standard.
- Potential for transferring patient information and adjusting system settings by using the USB port for connecting to a PC.
- Possibility of both vertical and horizontal installation.

Section 1 – Principles of Operation

1-1- Safety

Read this section carefully before use.

1-1-1- Intended use

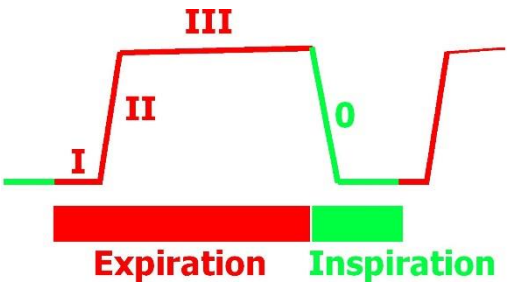
The ACCUCAP911 device is used to measure $EtCO_2$, $FiCO_2$ and Respiration Rate factors.

1-1-2- Operating principles

- The capnography uses infrared spectrometry (IR) to measure carbon dioxide concentration.
- The wavelength of infrared light exceeds 1 millimeter while the visible light spectrum is between 0.4 and 0.8 millimeter. Infrared light is absorbed by polyatomic gases (non-basic gases such as nitrogen oxide (N_2O), carbon dioxide (CO_2), and water vapor).
- Carbon dioxide selectively absorbs IR light at a specific wavelength, approximately 4.3 millimicrons. As long as the amount of absorbed light is proportional to the concentration of CO_2 molecules, the gas concentration can be calculated by comparing the measured absorbance with the standard absorbance.

1-1-3- Capnography waveform

The capnography waveform, which is time-based, can be divided into two primary phases: inhalation (zero phase) and exhalation. Similar to the nitrogen or carbon dioxide curves of a simple breath, the exhalation segment is further divided into phases I, II, III and occasionally phase IV, which represents the final rise in carbon dioxide concentration. The angle between phase II and phase III is called alpha angle. Similarly, the angle between phase III and zero phase is called beta angle and is typically close to 90 degrees.



1-1-4- Warnings

⚠ A warning indicates the possibility of injury to the user or patient. This suggests that follow the warnings that are issued.

⚠ Make sure to read the instructions before use.

⚠ This device must be used by experienced employees after reading the instructions and getting familiar with the technical specifications.

⚠ The alarm range of the device automatically resets to the standard's specified limits after each power-on. Only if needed, adjust the desired range through the corresponding menu.

⚠ Only visual messages will show up on the screen if you disable auditory alarms. Please note that audio alarms will remain disabled on the device for maximum 120 seconds based on user settings.

⚠ If the patient is in critical condition, it is better not to disable the alarms.

⚠ Do not block the openings related to the device speaker. This will reduce the effectiveness of sound warnings.

⚠ Do not lift or move the device by its cable connection or sensor cable. In general, do not apply excessive tension to the sensors cable or pneumatic tubing.

⚠ Use only CAPNOSTAT® 5 or LoFlo® sensors for this device. Using sensors from other manufacturers will cause improper performance or damage to the device.

⚠ If damage is observed in the sensor, refrain from using it. Do not attempt to sterilize sensors by autoclave.

⚠ If the LCD screen of the device is broken, take extra care to keep the liquid away from your body. These chemicals are extremely harmful and poisonous**.**

⚠ If there is a defect in the sensor, do not use it and contact the service department of your medical center or the company's service department.

⚠ The sensors of this device and their accessories cannot be autoclaved.

⚠ Do not use the device in the presence of flammable anesthetics. Use of the sensors in such environment may present an explosion hazard.

⚠ If the sensors fail to respond as described in this user guide; do not use it until approved for use by the qualified personnel of Parsian Medical Co.

⚠ Check the air tube of the sensor for blockage, any damage, traces of blood or dirt. If any of these cases are observed, this tube should be changed.

⚠ If the device fails to communicate with the sensor, immediately notify the service department of your medical center or the service department of the Parsian Medical Co.

⚠ If a serious incident occurs in relation to the device, please report to the Parsian Medical Co. and the competent authority of the member state in which the user and/or patient is established.

Risk of explosion: Do not use this device in environments containing flammable anesthetic gases or other flammable gases, especially when combined with air or a mixture of oxygen and nitrogen in enclosed environments.

1-2- Security

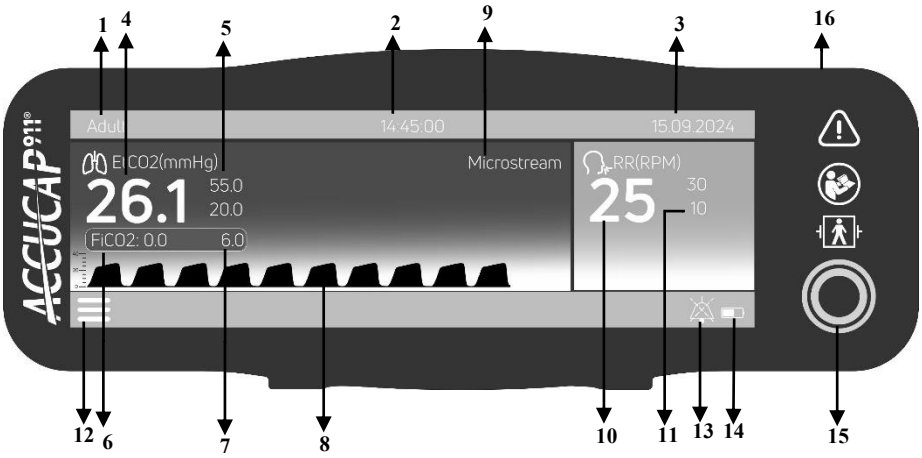
1-2-1- Caution

- Attention indicates the possibility of damage to the device or its inefficiency**.**
- This device can only be used for medical purposes**.**
- The ACCUCAP911 is equipped with a rechargeable Li-ion battery. Do not attempt to replace or remove the battery from the device. Refer service to qualified service

personnel. Disposal of the battery and other accessories should comply with national and/or local requirements.

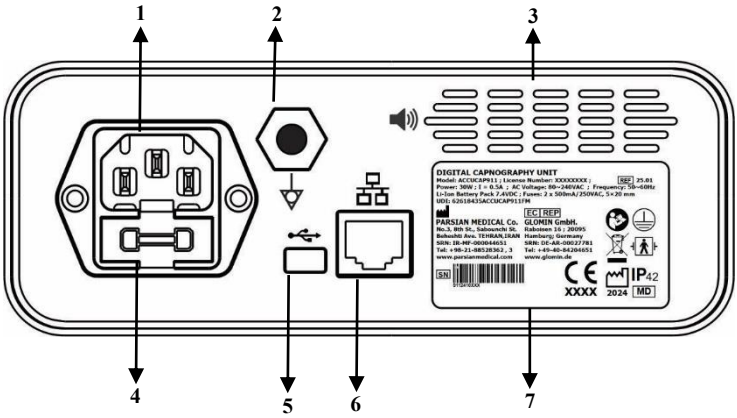
- Do not use the ACCUCAP911 during magnetic resonance imaging (MRI).
- If there is a fault in device or any serious incident that has occurred in relation to the device, do not use it and send it to Parsian Medical Co. for repair as soon as possible.
- Do not unscrew the device under any circumstances. There is no part inside the device to be adjusted by the user. In addition to voiding the device's warranty, this will also cause harm to the patient.
- Do not expose the device to direct water splashes or drops (for example, in the rain).
- Check the sensor cable for physical damage before use.
- Avoid moving the device by pulling the cables.
- To prevent any potential injury to the patient, select an installation location where the device cannot accidentally fall on them.
- This device can be used in conjunction with defibrillators or high frequency surgical devices. However, this may affect the accuracy or availability of the parameters and measurements.
- If the power outlet used does not have a protective earth pin or this pin is not connected, it is better to connect the equipotential ground conductor pin on the back of the device to the protective earth of the power grid using a screw clamp.
- To avoid the risk of electric shock, use a standard earthed power cable (power cable equipped with the device).
- Check the device time and date in the relevant menu before using the trend menu.

1-2-2- Signs and icons description



1	Patient range	2	Time (hour, min, sec)
3	Date (day, month, year)	4	$EtCO_2$
5	Upper and lower limits of $EtCO_2$	6	$FiCO_2$
7	Upper limit of $FiCO_2$	8	Capnography waveform
9	Sensor type indication	10	Respiration Rate (RR)
11	Upper and lower limits of RR	12	Menu
13	Alarm silence	14	Battery charge percentage
15	Capnography sensor connector	16	ON / OFF key and alarm indicator

1-2-3- Backside connectors

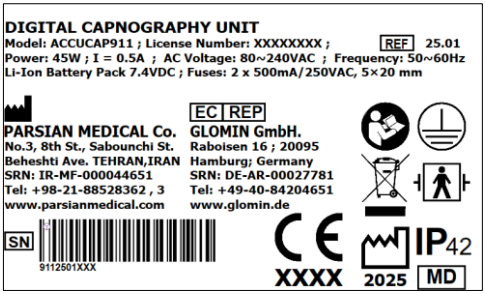


1	Power connector	2	Equipotential ground connector
3	Speaker	4	Fuse holder
5	Mini-USB	6	RJ45 Ethernet connector
7	System information label		

1-2-4- Symbols

	Defibrillation-proof. Type BF applied part		Production year
	Follow instructions for use	IP42	Protection from ingress of particulates > 1 mm and against vertically falling water drops when it tilted at 15 degrees
	Separate collection for electrical and electronic equipment		Manufacturer
SN	Device serial number		Protective earth (Class I equipment)
EC REP	EU Authorized representative	REF	Catalog number
CE	CE Mark	MD	Medical device

1-2-5- Device label



1-3- Sensors and accessories

This system is only compatible with PHILIPS RESPIRONICS sensors, which one of the specified sensors and an airway adaptor being packaged with the device according to the customer's demand. The list of these sensors with degree of protection IPX4 is given below.

Patient	Sensor
Adult, Pediatric, Neonatal	CAPNOSTAT 5
Adult, Pediatric, Neonatal	LoFlo

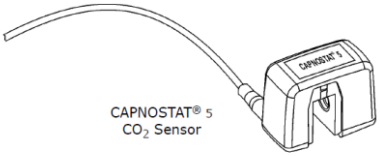
The following points should be considered regarding to the sensors:

- CAPNOSTAT 5 sensor is a Mainstream type and LoFlo sensor is a Microstream type.
- In the presence of electromagnetic devices (i.e., electrocautery), device may be interrupted due to electromagnetic interference. Electromagnetic fields up to 20 V/m will not adversely affect system performance.
- Neither users nor medical center service professionals are able to fix or modify the sensors on this device. Never open the sensors.
- Components of this device and its associated accessories which have patient contact are free of latex.
- The sensors should be disposed of in compliance with electronic waste standards, as they contain electronic circuits.
- Nitrogen oxide, high concentration oxygen, helium and halogenated hydrocarbons can cause errors in CO_2 calculation.
- Barometric pressure compensation is required to meet the stated accuracy of the device sensor.
- As with all flow measuring devices, adverse conditions may affect the accuracy of the flow measurement.
- Do not place the combined CO_2/flow sensor between the endotracheal tube and the elbow (pediatric/ adult circuit), as this may allow patient secretions to block the adapter windows.

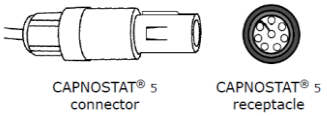
- For LoFlo sensors, ensure the pipe connecting to the breathing path is positioned vertically relative to the flow path. This helps prevent moisture and other liquids from accumulating and infiltrating, which could saturate the dehumidifier filter or block the path.
- Periodically check the pipes and breathing passages so that there is no trace of moisture or liquid inside them.
- To clean the airway adapter, use a cotton swab dipped in 70% isopropyl alcohol solution.
- The sensors of this system have a maximum calibration period of one year. The accuracy of sensor performance can only be confirmed through calibration tests, and if the sensor fails the test, it must be replaced.

1-3-1- CAPNOSTAT 5 Sensor

This section provides information regarding the CAPNOSTAT 5 CO_2 sensor and its use with CO_2 airway adapters. To use this sensor, just follow the steps below in order.



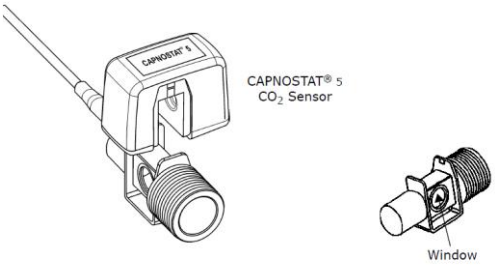
1. Insert the CAPNOSTAT 5 CO_2 sensor connector into the receptacle of the device as shown below.



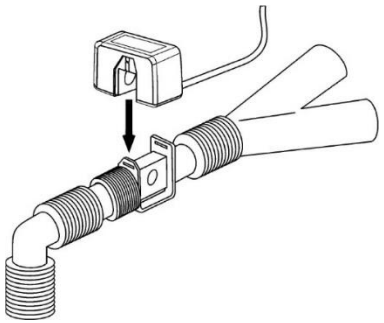
2. Make sure the arrows on the connector are at the top of the connector and line up the two keys of the connector with the receptacle and insert.
3. To remove the connector, grasp the body portion of the connector back and remove.

Note: Do not remove by pulling cable.

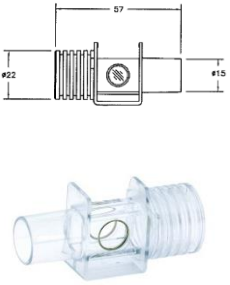
Shown below is the CAPNOSTAT 5 CO_2 sensor connection to an adapter. For this, slide on the adapter and click into place. To remove the adapter, just slide it off.

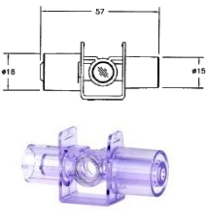
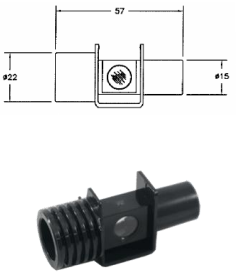
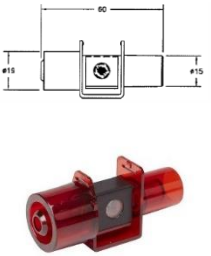


Shown below is the CAPNOSTAT 5 CO_2 Sensor with a patient circuit:



For monitoring CO_2, select an airway adapter based on the patient and monitoring situation as described in the table below.

Model	Description	Figure
6063	Pediatric/Adult single patient use airway adapter • For intubated patients with endotracheal tube diameters greater than 4 mm • Adds 5 CC of dead space • Weight: 7.7 g • Pressure drop: 0.40 cmH_2O @ 60 LPM • Color: Clear	

6312	Infant/Pediatric single patient use airway adapter • For intubated patients with endotracheal tube diameters less than 4 mm • Adds less than 1 CC of dead space • Weight: 9.1 g • Pressure drop: 0.74 cmH_2O @ 10 LPM • Color: Purple	
7007	Pediatric/Adult reusable airway adapter • For intubated patients with endotracheal tube diameters greater than 4 mm • Adds 5 CC of dead space • Weight: 12.0 g • Pressure drop: 0.38 cmH_2O @ 60 LPM • Color: Black	
7053	Infant/Pediatric reusable airway adapter • For intubated patients with endotracheal tube diameters less than or equal to 4 mm • Adds less than 1 CC of dead space • Weight: 14.9 g • Pressure drop: 0.68 cmH_2O @ 10 LPM • Color: Red	

Section 2 – Instruction for installation and usage

2-1- Preparation for use

1. Unpack the device and make sure that there is no evidence of damaging on the device and its accessories.
2. Check the sensor cable and the sensor connector and make sure there is no evidence of damaging or defective pin on their connectors.
3. Open the sensor package and make sure it is intact.
4. Hold the button ⏻ for 2 seconds until the Parsian Medical Co. logo appears on the screen and hear the welcome sound.
5. After connecting the power cable to the device, make sure that the symbol is displayed on the screen.
6. Connect the sensor cable to the device. The “Sensor Warming Up” warning will appear.
7. After the sensor warms up and the “Sensor Warming Up” warning is cleared, you should see the amount of $EtCO_2$ and RR on the screen (time response).
8. You can set the upper and lower limits of $EtCO_2$, $FiCO_2$ and RR measures by touching these limits on the screen. Check these issues and make sure it’s working correctly.
9. Disconnecting the sensor cable from the device will display “Sensor Disconnected” on the screen. Check the occurrence of this condition**.**

2-2- Quick manual

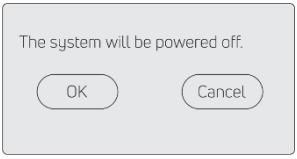
- Press the button  to turn on the device. The device turns on after displaying the logo of Parsian Medical Co. and playing the welcome sound.
- To turn off the device, press  and hold the button. Then you should choose Yes to turning system off.
- Use the  to access the settings menu.
- To change the patient age range, select  from the main menu or touch the corresponding option in the upper left part of the screen. Three options, Adult, Pediatric, and Neonate, will appear on the screen to select the age range of adult, pediatric, and neonate, respectively.
- By selecting  , you can change the capnograph's settings.
- By selecting  , you can enter the menu related to registering patient information per time unit (second).
- Use  to silence auditory alarms temporarily.
- Touch the battery symbol  to check the percentage of battery power.
- To calibrate the zero point of the sensor, use the "Zero Calibration" option in the capnograph settings menu.

2-3- User manual

2-3-1- Turning device on and off

To turn on the device, press ⏻ button until the Parsian Medical Co. logo appears on the screen, and the welcome sound plays**.**

To turn off the device, press and hold the same button. After confirmation, the Parsian Medical Co. logo and a “Power Off” message will appear on the screen**.**



2-3-2- Main power and battery

When the power cable is connected to the power cord inlet on the back panel, a sign will appears on the device's display screen. During charging, if the device is turned off, the alarm indicator will turn red, and, its color will change to green gradually as the battery charge increases.

Touch the battery icon to check the remaining battery level. The battery icon provides a visual indication of the current battery charge condition as follow:

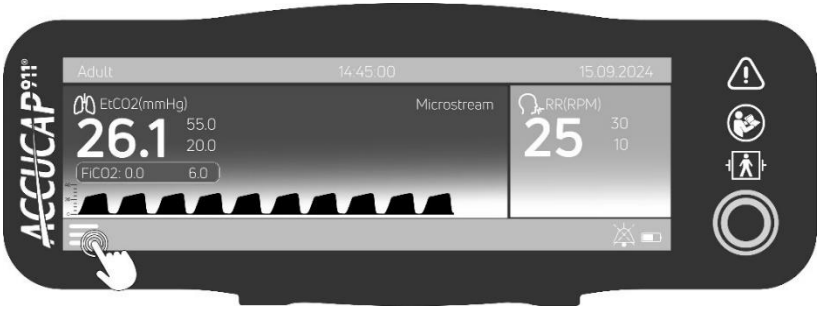
Displayed symbols												
Charge percentage	<10	10	20	30	40	50	60	70	80	90	100	connect the power cable

2-3-3- Connecting the sensor to the device

Connect the sensor connector to the device according to the specified direction, following the connector guide. Two arrows in opposite directions indicate the alignment for connecting and disconnecting the connector. Self-latching system allows the connector to be mated by simply pushing the plug axially into the socket. If the connector is connected properly, the message “Sensor Disconnected” will change to “Compensation,” followed by “Sensor Warming Up.” If the message “Compensation” is repeatedly displayed on the device, disconnect the sensor from the device and reconnect it. If this problem is repeated, contact this company. With the device's default settings, available in the sensor settings menu, you can begin the monitoring process by connecting the sensor to the patient's respiratory circuit.

2-3-4- Setting menu

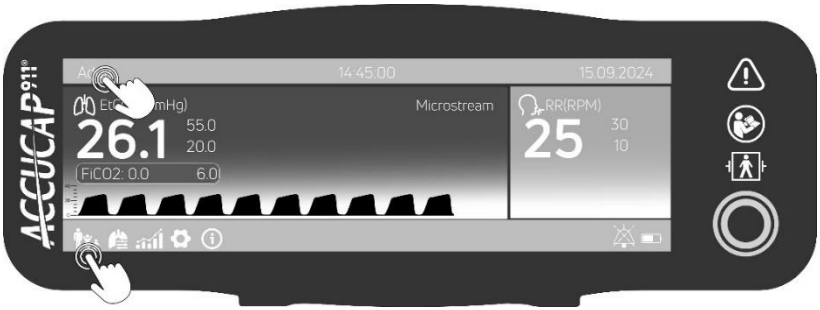
Access the settings menu by touching ≡ on the screen. Then, select the desired option from the choices that appear in bottom left corner of the screen. If you touch any point outside the settings menu on the screen, you will exit from it.



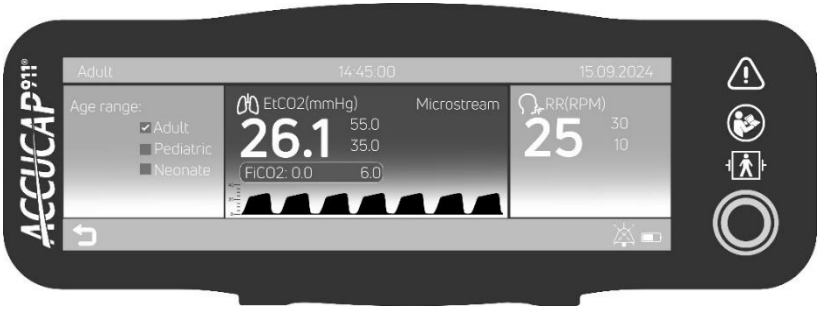
Note: The desired menu will automatically close after 90 seconds, if no modifications or selection are made by the user.

2-3-5- Patient mode

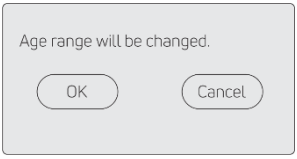
This device can be adjusted for three age ranges of the patient: Adult mode for older patients or those weighing more than 50 kg, Pediatric mode for younger patients weighing between 20 kg and 50 kg, and Neonate mode for newborn patients weighing below 20 kg. By adjusting the patient range correctly, you can observe more accurate measurements. To change the age range to adult, pediatric, or neonate, touch the corresponding option in the upper-left side of the monitor or select from the main menu.



Immediately, three options, Adult, Pediatric and Neonate, will appear on the screen. Select the desired option on the screen by touching it**.**



After selecting the age range of the patient and choosing the return option, the following message will appear on the screen. Select OK if you assure about your choice; otherwise, choose Cancel.



2-3-6- Upper and lower limits of $EtCO_2$, RR, and $FiCO_2$

In order to set the upper and lower limit of auditory and visual alarms of $EtCO_2$, RR, and $FiCO_2$, select upper and lower limits of each value**.**

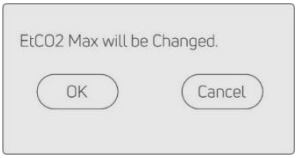
The following thresholds are suggested for each age ranges**:**

Adult Mode	
Limit	Value
High $EtCO_2$ (mmHg)	55.0
Low $EtCO_2$ (mmHg)	15.0
High $FiCO_2$ (mmHg)	6
High RR (RPM)	24
Low RR (RPM)	10

Pediatric Mode	
Limit	Value
High $EtCO_2$ (mmHg)	55.0
Low $EtCO_2$ (mmHg)	15.0
High $FiCO_2$ (mmHg)	6
High RR (RPM)	35
Low RR (RPM)	15

Neonate Mode	
Limit	Value
High $EtCO_2$ (mmHg)	55.0
Low $EtCO_2$ (mmHg)	15.0
High $FiCO_2$ (mmHg)	6
High RR (RPM)	60
Low RR (RPM)	25

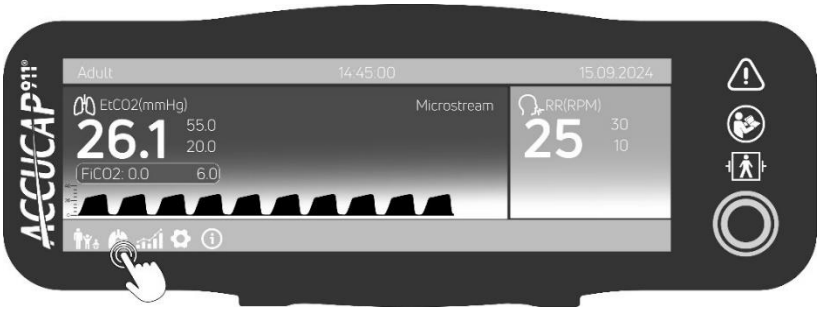
After selecting the upper or lower limit of each parameter and choosing the return, the following message will appear on the screen. Select OK if you assure of your selection; otherwise, choose Cancel.



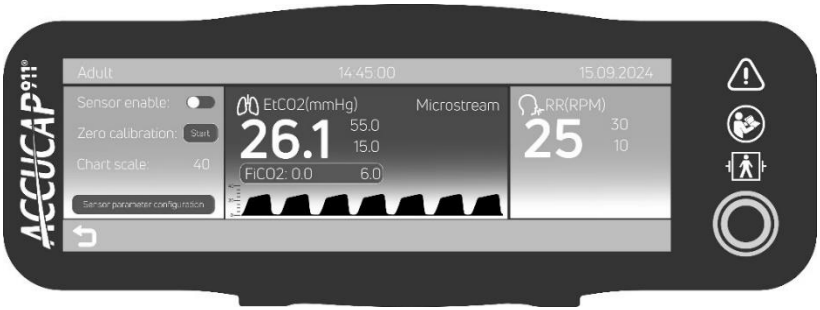
Warning: Users should be warned that modifying the alarm's ranges can pose a risk to patients in specific medical situations. Remember that alarms may lose their effectiveness under high-priority condition. Note that the upper and lower alarm limits for all patient age groups (adult, pediatric, and neonate) will reset to the default values after the device is turned off and on. Additionally, the color of the measured parameters values that fall outside of the set range will change to red for the special user's attention.

2-3-7- Capnography settings

To access the capnograph settings menu, touch the option after choosing the main menu**.**

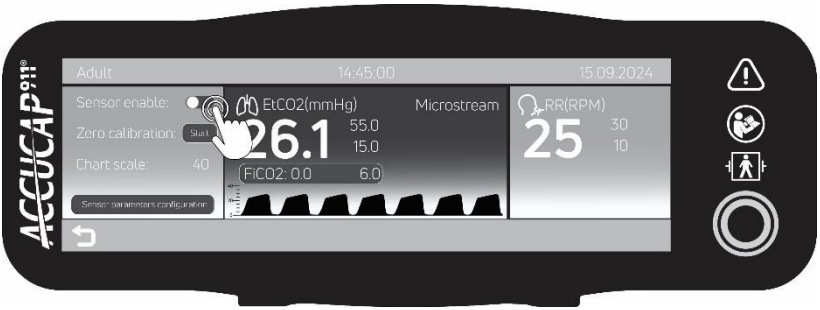


This menu contains all settings related to the capnography system's performance, including enabling or disabling the sensor, zero-point calibration, adjusting the capnograph waveform scale, and configuration the capnograph sensor for $EtCO_2$ calculation.



2-3-8- Enable and disable capnograph sensor

In the capnography settings menu , you can turn the sensor on or off when the device is powered on but the capnography sensor is not in use. By deactivating the sensor, the message “Sensor Disabled” is displayed, and by activating the sensor, this message changes into “Sensor Connected.”



2-3-9- Calibration zero-point of the sensor

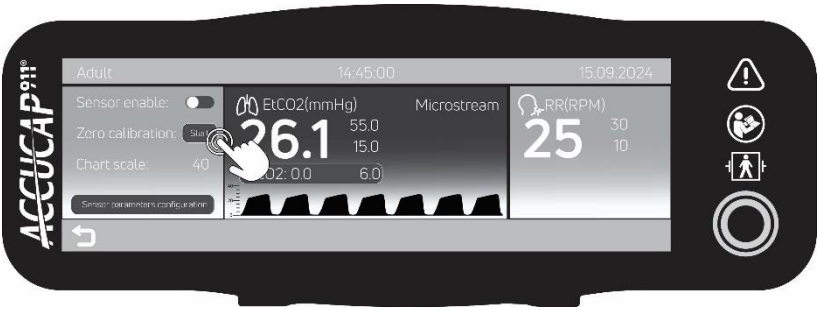
This menu is used to calibrate the zero-point of the sensors after replacing their consumable parts (pipes and respiratory tract adapters). Normally, the calibration process will last 15-20 seconds, with a maximum duration of 40 seconds.

It is recommended to wait at least two seconds to start the calibration process after replacing the consumable parts of the sensors. In order to properly complete the calibration process, the following steps must be implemented:

1- Connect the consumable parts of the sensor (pipes and respiratory tract adapters) to it. Place the sensor in the monitoring room, ensuring it is away from any of the carbon dioxide sources, the ventilator outlet, and the exhaled air from patient or yourself.

2- Connect the sensor to the device and wait until the “Sensor Warming Up” message is cleared.

3- On the capnography settings menu on the main menu of the device, select the Start option related to “Zero calibration.”

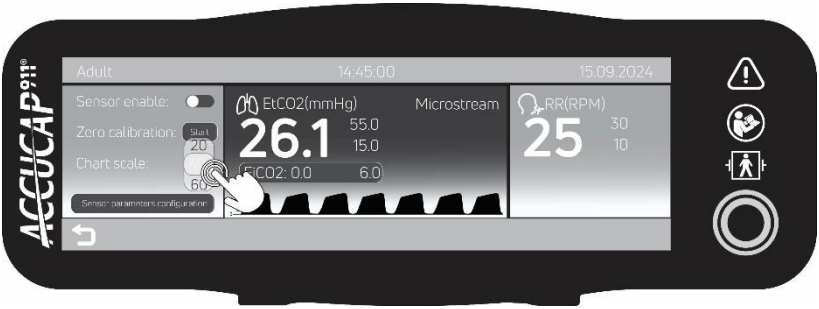


Note: If this process takes longer than 60 seconds, there may be an issue with your sensor. Please contact Parsian Medical Co. for service.

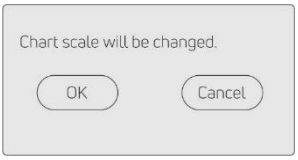
2-3-10- Capnograph waveform scale

To adjust the resolution of the capnography waveform in the capnograph settings menu, touch the number corresponding to the term “Chart scale” and change the scale by scrolling it up and down. You will also access this menu by selecting the scale column in the capnography waveform. The adjustable values, based on the $EtCO_2$ measurement unit, are as follows**:**

Unit	Scale
%	2, 6, 8, 12
KPA	2, 6, 8, 12
mmHg	20, 40, 60, 90

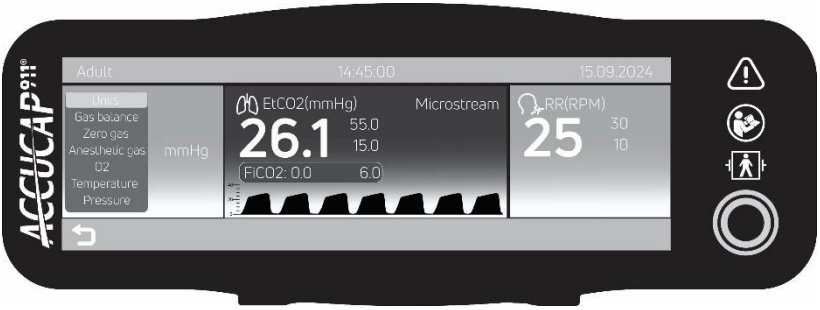


After selecting the desired value by choosing or touching any point on the screen, the following message will appear. Select OK if you assure about your choice; otherwise, choose Cancel.



2-3-11- Capnograph sensor configuration

It is possible to modify the device settings used for calculating measured values by accessing the capnograph settings menu and selecting the "Sensor Parameters Configuration" option.



The values shown in the table below can be adjusted within this menu**:**

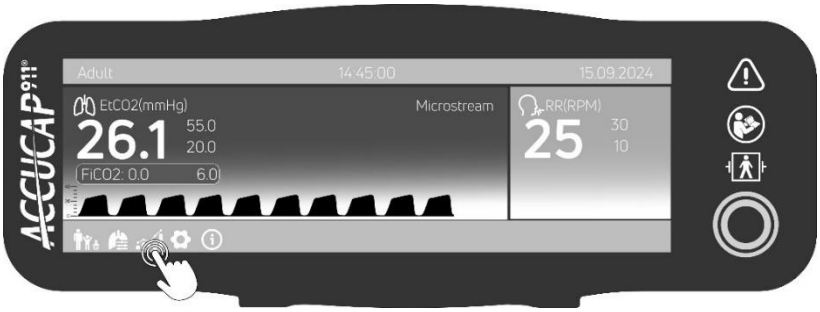
Parameter	Values	Description
Units	mmHg, KPA, %	This parameter determines the measurement unit for $EtCO_2$.
Gas balance	Air, N_2O, Helium	The breathing gas combination is selected with one of the specified gases in this setting, which impacts the carbon dioxide saturation calculations.
Zero gas	N_2, Air	The desired gas for zero-point calibration is specified in this section.

Expired Gas Compensation		
Parameter	**Values**	**Description**
Anesthetic gas	0.0%-20.0%	Configuration of the compensation coefficient for $EtCO_2$ measurement based on the determined value.
O_2	0%-100%	Configuration of the compensation coefficient for $EtCO_2$ measurement based on the determined value.
Temperature	0 – 50 ºC	Configuration of the compensation coefficient for $EtCO_2$ measurement based on the determined value.
Pressure	400-850 mmHg	Configuration of the ambient air pressure is stored in the device memory. If the set air pressure value differs from the value measured by the device, an option to "Set pressure automatically" will appear for adjustment.

After adjusting the desired value by selecting ⮌ or tapping any point on the screen, confirm your choice by selecting **OK**. If you wish to discard the change, select **Cancel.**

2-3-12- Set patient information to store parameters (Trend)

Select the settings menu ≡ on the screen and then 📈. In this case, you can store $EtCO_2$, $FiCO_2$ and RR values for each patient in the terms of time (second)**.**



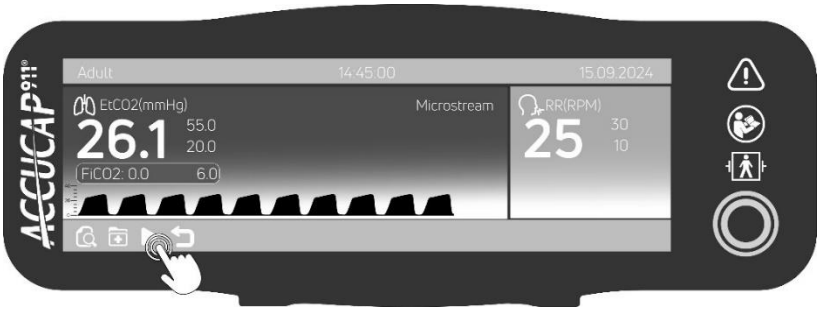
Next, choose . In this menu, you can enter the patient's first name, last name, file name, age, and gender using the on-screen keyboard by tapping any of the fields.

First name
Last name
File
Age
Gender

You can return to the previous menu by selecting or you will exit the settings menu by touching any point outside displayed menu. If trend is running, it is not possible to access this menu.

2-3-12- Start storing parameters (Trend)

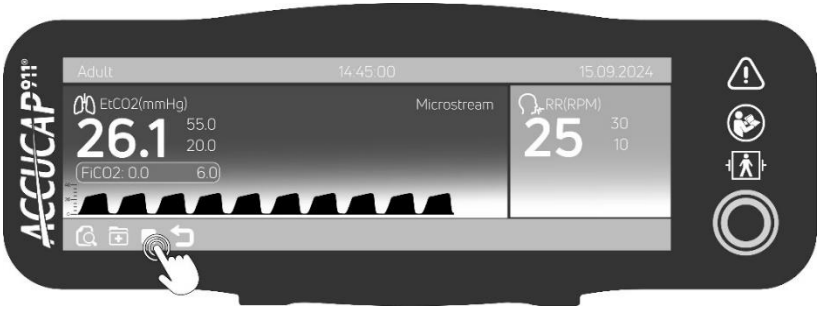
Select settings menu on the screen and then . Enable trend by touching . Note that when this option is activated, the symbol Trend will appear on the screen.



Note: It is not possible to change the unit of the $EtCO_2$ when trend is started.

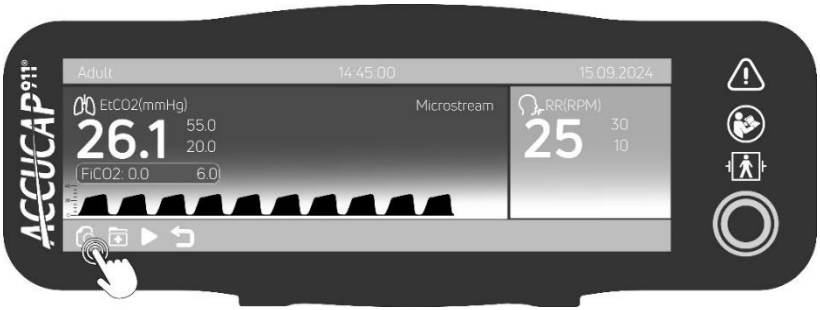
2-3-13- Stop trend

From settings menu ≡ on the screen, select . Then disable trend mode by touching ■.



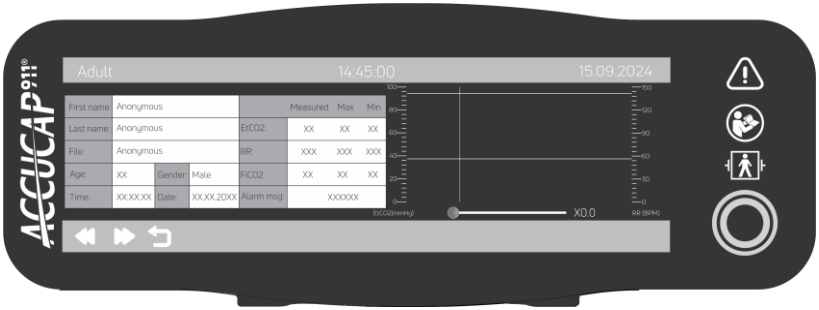
2-3-14- View and review trends

From settings menu ≡ on the screen, select . Then select to reach the corresponding menu.



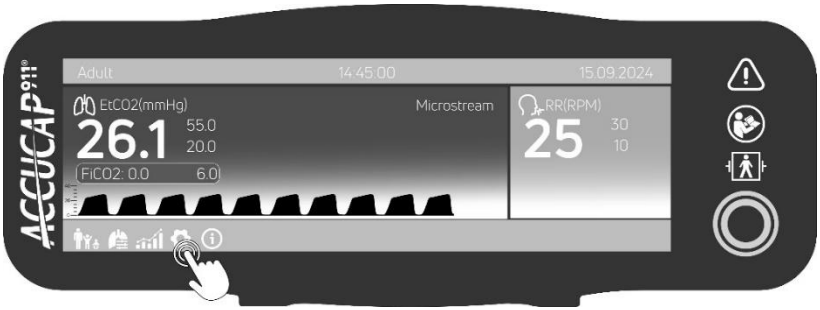
In this menu, the patient's information is shown in menu both in a table and also on a graph. To move on the graph, you can use the or . In case of continuous touching of these options, the speed of movement of the indicator on the graph will increase. This feature is useful for reviewing charts recorded over longer periods.

Using the Zoom scroll bar under the graph, it is possible to enlarge the desired part of the graph up to ten times. For this purpose, scroll right or left**.**

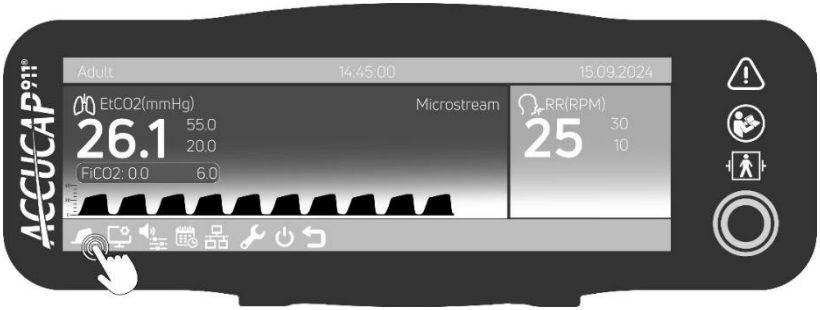


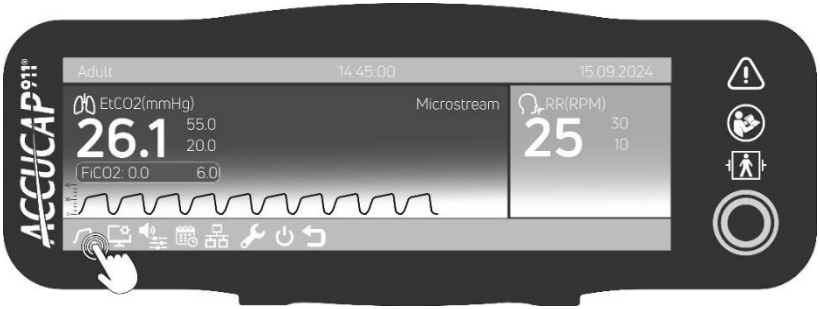
2-3-15- Setting the waveform shape

From settings menu on the screen, select **.**



By choosing  or  you can change the capnography waveform shape. In addition, every time you touch the chart on screen, the waveform shape will change.

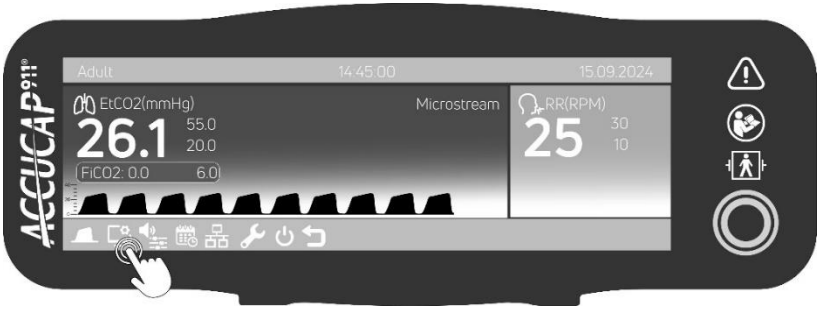




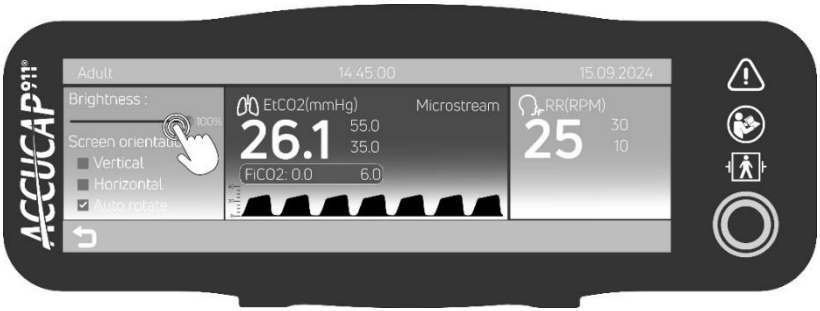
Select  to return to the main menu. If you touch any point outside the settings menu on the screen, you will also exit from this menu.

2-3-16- Screen settings

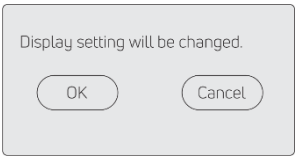
Choose settings menu on the screen and select and then .



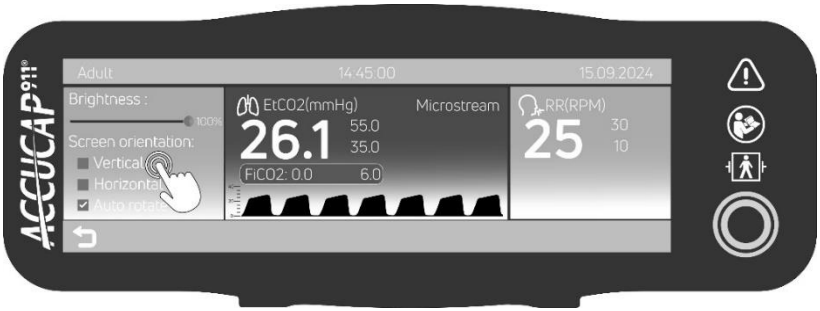
In this menu, the intensity of the backlight can be changed from ten percent (10%) to one hundred percent (100%) in each ten percent steps. For this purpose, scroll left or right**.**



If you wish to cancel or exit the settings, select to return to the previous menu. If you touch any point outside the settings menu on the screen, you will also exit it. Select OK if you assure of your selection; otherwise, choose Cancel.

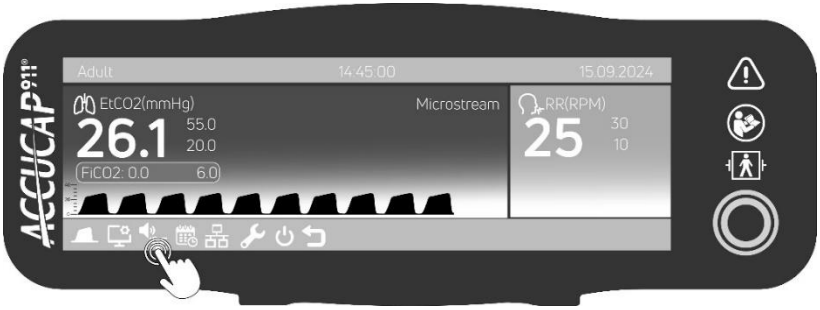


In this device, the screen content can automatically adjust by rotating the device vertically or horizontally, unless the user decides to disable this feature and choose screen orientation manually. For this purpose, select the desired mode in the screen settings menu  one of the “Vertical”, “Horizontal”, or “Auto rotate” options and then confirm your decision**.**

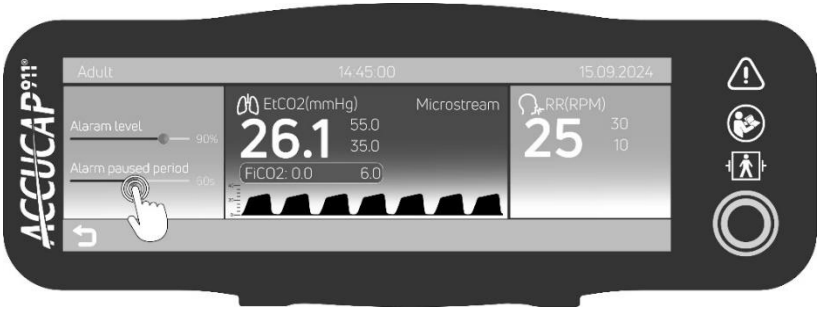


2-3-17- Sound setting

From settings menu on the screen, select the option . Then choose to change the audio setting.

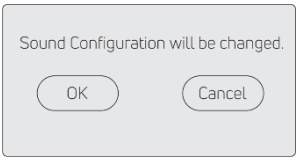


In this menu, the volume of the sound alarms (Alarm level) and temporarily inactivation the generation of alarm signal (Alarm paused period) can be adjusted according to the following table by scrolling each option right or left**.**

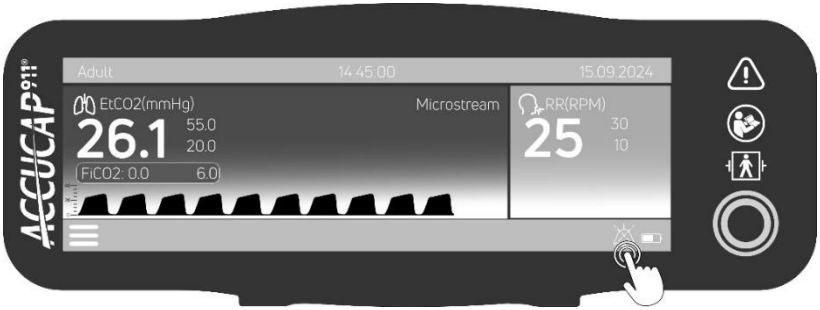


	Range	Step	Unit
Alarm level	10 – 100	10	Percentage
Alarm paused period	0 - 120	30	Second

If you wish to cancel or exit the settings, select to return to the previous menu. If you touch any point outside the settings menu on the screen, you will also exit it. Select OK if you assure of your selection; otherwise, choose Cancel.

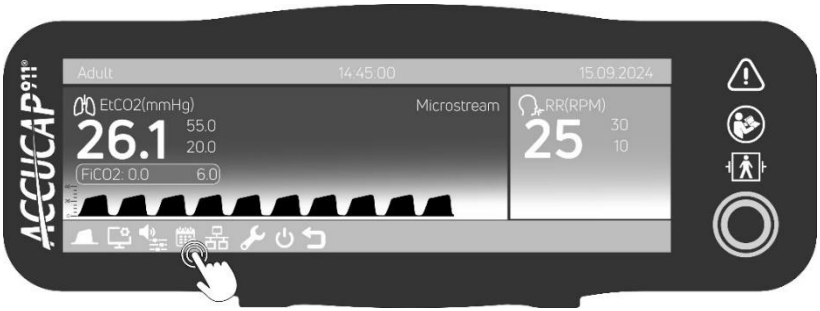


Additionally, selecting  causes temporarily inactivation the generation of alarms audio (alarm paused) for a period of time (adjustable interval up to 120 seconds). Selecting this option again terminates it.

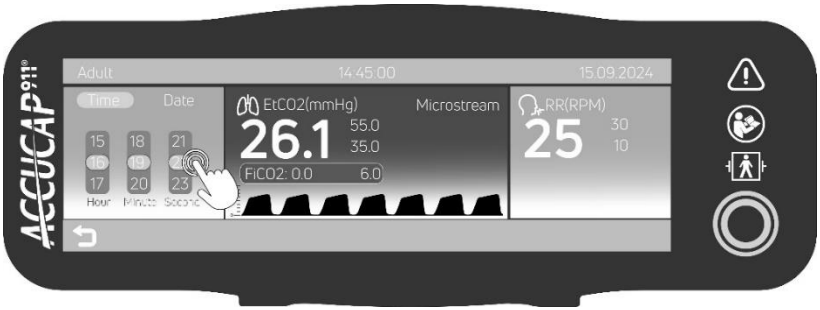


2-3-18- Set time and date

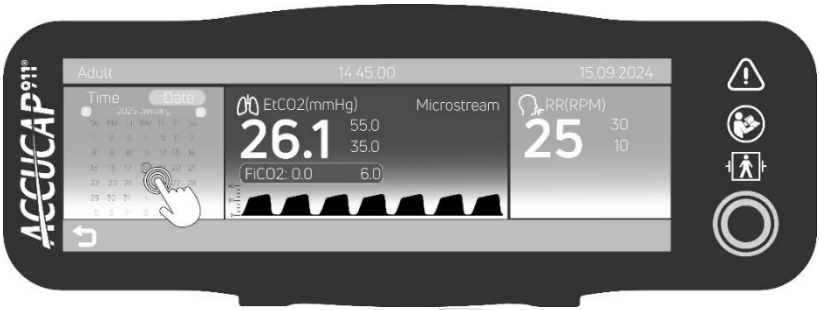
Select settings menu  on the screen and then  . Choose  to set the time and date .



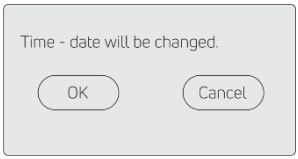
In this menu, you can change the time by setting the Hour, Minute, and Second with scrolling related items up and down.



You can also set Day, Month, and Year in the Date tab in the same menu.

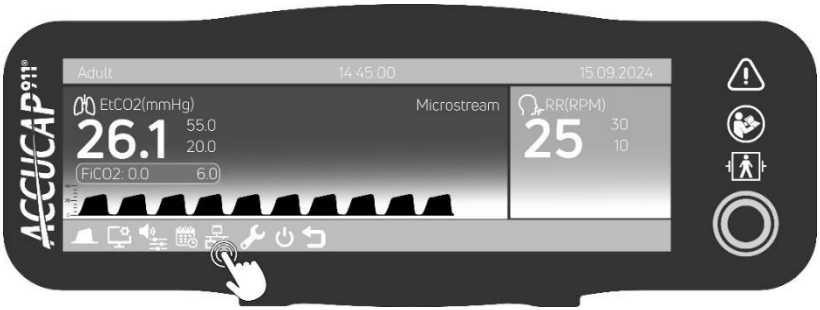


If you wish to cancel or exit the settings, select to return to the previous menu. If you touch any point outside the settings menu on the screen, you will also exit the settings menu. Select OK if you assure of your choice; otherwise, choose Cancel.

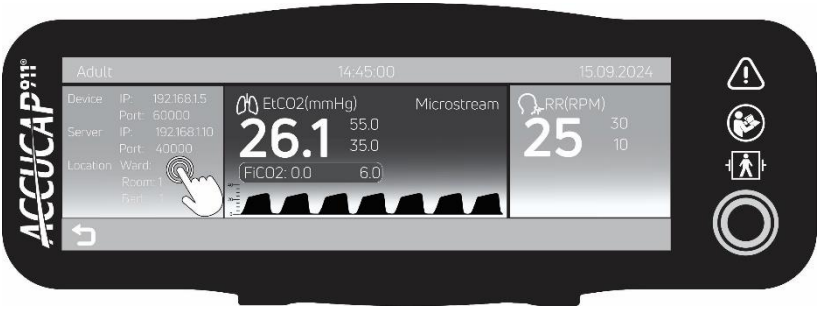


2-3-19- Ethernet

In settings menu on the screen, select . Then, you can change the network settings menu.

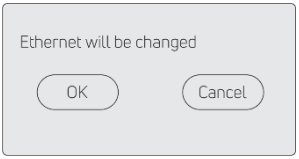


In this menu, you can change Device IP, Server IP, Ward location, Room, and Bed numbers.



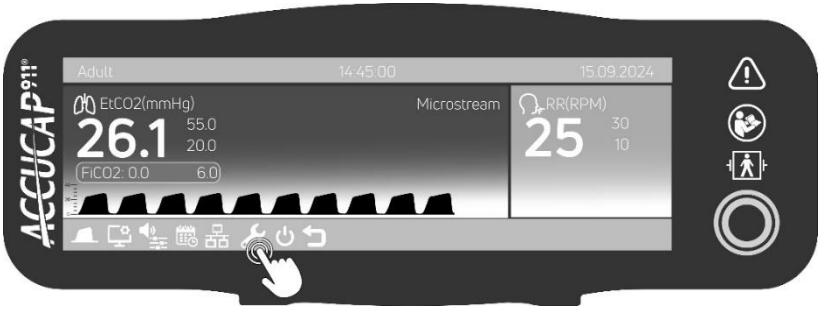
In this case, Device IP and Port in the first row are related to device settings and in the second row are related to the specifications of the HL7 server that receives the information sent by the devices. Based on the HL7 standard, all required parameters such as ward name (Location Ward), room number (Room) and bed number (Bed) will also be sent and utilized in the integrated clinical environment (ICE). By connecting the device to the Ethernet network, it will automatically communicate with the HL7 server and all the required fields will be sent to the server according to the mentioned standard.

Select ⮌ to return to the previous menu. If you touch any point outside the settings menu on the screen, you will also exit the settings menu. Select OK if you assure of your selection; otherwise, choose Cancel.



2-3-20- Service

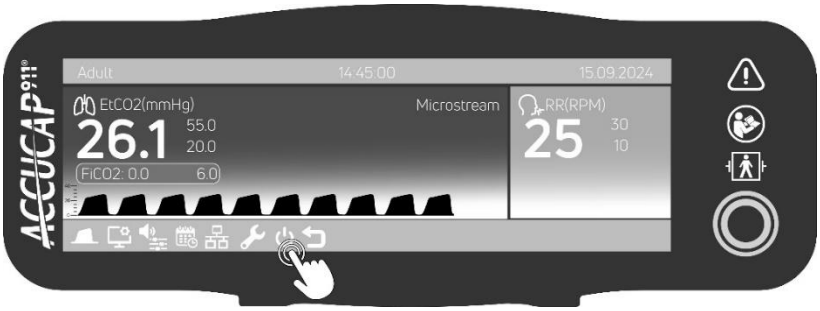
Only authorized service personnels are granted access to menu. It contains special parameters regarding the device hardware.



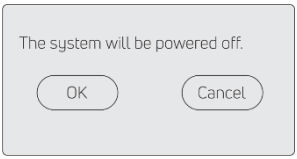
2-3-21- Turn off the device using the setting menu

To turn off the device without using the on and off button, from , select menu .

Then, select icon.

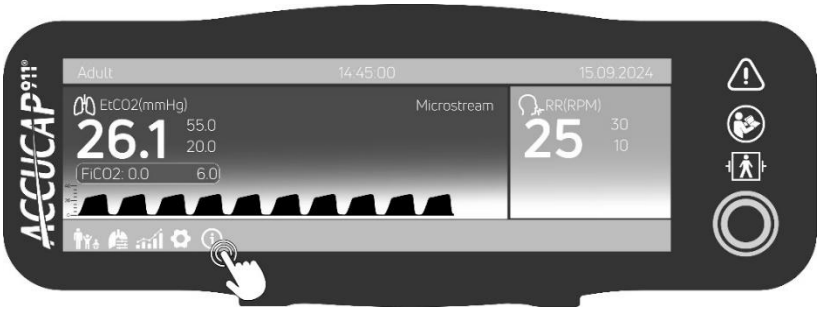


If the displayed message is confirmed, the Parsian Medical Co. logo and a “Power Off” message will appear on the screen.

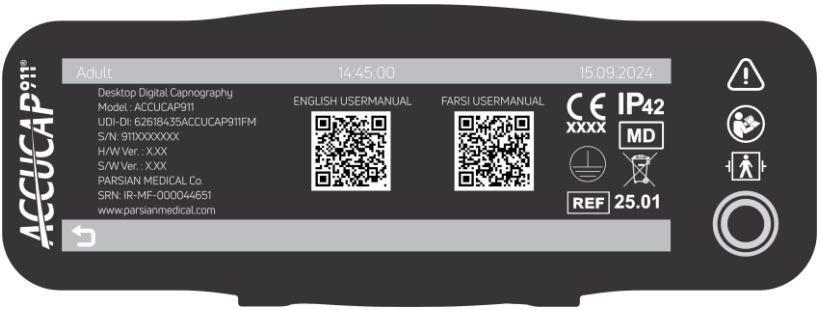


2-3-22- System information

This menu is used to check the general specifications of the device including hardware and software versions and serial number. In this case, select ≡ on the screen, choose the settings menu and then ⓘ.



The following items will be displayed. Select ⮌ to return to the main men or touch any other point on the screen than menu area.



Desktop Digital Capnography	Equipment name
Model	Equipment model
UDI-DI	Unique device identification in the EU
S/N	Serial number
H/W Ver	Hardware version
S/W Ver	Software version
Parsian Medical Co.	Manufacturer
SRN	Manufacturer single registration number in the EU
www.parsianmedical.com	Website of manufacturer

By scanning the QR code displayed on the screen with your mobile phone, you can access the device's user manual online.

2-3-23- USB port communication

To connect to the computer via the USB port, you need to use a special USB cable, with a plug on each end —one Mini-B and one A— which the corresponding receptacle is on a computer. Once connected to the computer and after installing the necessary software, you can save the device information to the computer. For instructions on connecting via USB, refer to the manual.

2-3-24- Data accuracy assurance

To ensure the accuracy of measured factors, calculate the respiration rate manually using a timer and compare it with displayed RR. If there is a significant difference, the $EtCO_2$ factor may not be displayed correctly. In such a case, pack the device and the sensor, then contact Parsian Medical Co. service department to send it back for service.

2-4- Collect

- To turn off the device, hold the button ⏻ for 2 seconds and confirm power off message. The device will turn off after displaying the Parsian Medical logo and the Message “Power Off.”
- Disconnect the sensor connector from front panel.
- Separate the consumable parts of the sensor, including the connecting piece to the airway and the sampling tubes from the sensor.

2-5- Disposing conditions

In order to dispose the device, keep in mind that all conditions related to the disposal of electronic waste must be taken into account. The components of this device, such as the liquid crystal in the LCD screen and lithium batteries, contain hazardous chemicals that must be disposed of in accordance with specified conditions and regulations related to this type of waste. The relevant symbol for this waste indicated on the backside panel.

3-1- Technical specification

Note: All specifications are nominal values.

Sensor's Specifications	
Transducer Type	CAPNOSTAT® 5: **Mainstream** LoFlo®: **Microstream**
Principle of Operation	Non-dispersive infrared (NDIR) single beam optics, dual wavelength, no moving parts
Initialization Time	Displayed in less than 15 seconds for CAPNOSTAT® 5 and less than 20 seconds for LoFlo® at an ambient temperature of 25°C, full specifications within 2 minutes
CO_2 Measurement Range	0 to 150 mmHg 0 to 19.7% 0 to 20 KPA (at 760 mmHg)
CO_2 Calculation Method	BTPS (Body Temperature Pressure Saturated)
CO_2 Rise Time (10-90% of step change of final CO_2 value)	Less than 60 ms - Adult reusable or single-patient-use airway adaptor Less than 60 ms - Infant reusable or single-patient-use airway adaptor
CO_2 Resolution	0.1 mmHg 0 to 69 mmHg 0.25 mmHg 70 to 150 mmHg
CO_2 Accuracy (Temperature at 35° C)	0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% of reading 71 - 100 mmHg ± 8% of reading 101 - 150 mmHg ± 10% of reading
CO_2 Stability	Short Term Drift: Drift over four hours shall not exceed 0.8 mmHg maximum. Long Term Drift: Accuracy specification will be maintained over a 120-hour period.
CO_2 Noise	RMS noise of the sensor shall be less than or equal to 0.25 mmHg at 7.5% CO_2 for CAPNOSTAT® 5 and at 5% for LoFlo®.
Respiration Rate Range	0 to 150 breaths per minute (BPM)
Respiration Rate Accuracy	± 1 breath

Calibration	No routine user calibration required. An airway adapter zero is required when changing to a different style of airway adapter. Safety lock-outs: System does not allow adapter zero for 20 seconds after the last breath is detected. System does not allow adapter zero if temperature is not stable.	
$EtCO_2$ Calculation	Method: Peak of the expired CO_2 waveform Selections: 1 breath, 10 second, 20 second Note: the minimum reported differential value between the baseline and the CO_2 value shall be 5 mmHg.	
Inspired CO_2 Measurement	Range: 3 to 50 mmHg Method: Lowest reading of the CO_2 waveform in the previous 20 seconds Selection: 20 seconds (not user-selectable).	
Compensations	Compensations for: Expired O_2, balance gas (N_2, N_2O, He) and anesthetic agents Uses gas compensation information and barometric pressure to correct the raw carbon dioxide value.	
O_2 Compensation	Range: 0 to 100% Resolution: 1% Default: 16%	
N_2O Compensation	Range: 0 (Off) or 1 (ON) Default: Off Note: If ON, the balance of the mixture is O_2.	
He Compensation	Range: 0 (Off) or 1 (ON) Default: Off Note: If ON, the balance of the mixture is O_2.	
Total Pressure	Range: 400-850 mmHg Total pressure = Barometric plus Airway pressure	
Anesthetic Agent Effects (MAC levels)	Anesthetic Agent Sensitivity (uncompensated)	Accuracy specification will be maintained for halogenated anesthetic agents present at accepted MAC (Minimum Alveolar Concentration) clinical levels.

	Anesthetic Agent Sensitivity (compensated)	Testing at Agent levels defined by accepted regulatory standards (i.e., ASTM F1456, ISO 21647).
Cross-sensitivity Compensation Error*	0-40 mmHg: ± 1 mmHg additional error 41-70 mmHg: ± 2.5% additional error 71-100 mmHg: ± 4% additional error 101-150 mmHg: ± 5% additional error * Additional worse case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.	
Physical characteristics	CAPNOSTAT 5	Weight: 25 grams – CAPNOSTAT 5 CO_2 Sensor only; 78 grams CAPNOSTAT 5 CO_2 Sensor with cable and standard LEMO connector Size: 33 mm high x 43 mm wide x 23 mm deep 3 meters cable standard
	LoFlo	Module weight is less than 9.6 oz (272.16 g) Module Size: < 2.6" wide x 1.5" high x 3.5" deep [< 66.0 x 38.1 x 88.9 mm]

Additional notes regarding cross-sensitivity compensation errors:

Xenon: The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by an additional 5 mmHg at 38 mmHg.

Desflurane: The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg.

Ethanol, Isopropanol, Acetone, Methane: CO_2 accuracy will not be affected by the presence of 0.1% ethanol, 0.1% isopropanol, 0.1% acetone or 1% methane.

Quantitative effects of humidity and condensation: Full accuracy specifications will not be maintained for all non-condensing humidity levels.

Environmental	
Temperature and Humidity	Operating: 0 to 40°C, 10 to 90% RH, non-condensing Storage: -40 to 70°C, 10 to 90% RH, non-condensing
Atmospheric Pressure	Storage: 400-800 mmHg
Mode of operation	LoFlo CO_2 Module is rated for continuous use. No marking is required.
Category AP/APG	AP - This device is not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide
Water Resistance	IPX4 - Splash-proof
Shock Impact	IEC TR 60721-4-7 Class 7M3 (designed to withstand environments subject to significant vibrations or high shock levels) EN60068-2-27 Shock EN60068-2-64 Random Vibration

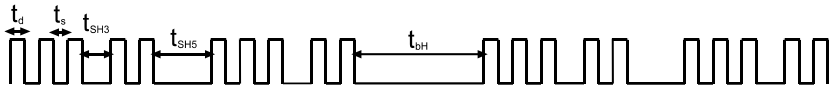
Display	
Type	High quality TFT full colors liquid crystal display (LCD) with LED backlight and capacitive touch
Data Displayed	$EtCO_2$, Respiration Rate, Capnography waveform, $FiCO_2$, Alarms and Status Messages
NOTE: There is no display delay from the calculated value.	

Alarm Limits	
Low $EtCO_2$	5-50 mmHg
High $EtCO_2$	20-80 mmHg
High $FiCO_2$	0.1-8 mmHg
Low RR	5-50 RPM
High RR	10-120 RPM

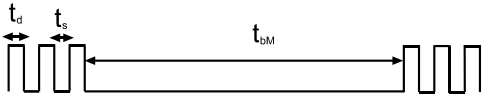
Physical Characteristic	
Dimension (WHD) Weight	25 × 8 × 22 cm 1 Kg

Characteristic of Auditory Alarm Signals According to IEC 60601-1-8:2006					
Pulse Frequency			700 Hz		
Effective Pulse Duration (t_d)	High Priority	50 ms	Pulse Spacing (t_S)	High Priority	50 ms
	Medium Priority	170 ms		Medium Priority	130 ms
t_{SH3}		150 ms	t_{bH}		10 s
t_{SH5}		550 ms	t_{bM}		20 s

High priority:



Medium priority:



Electrical Characteristics	
Power Requirement	80~264 VAC
Frequency Range	47~63 Hz
Rated Power	30 W
Fuse	2 x 500 mA/250 VAC, 5 x 20 mm
Battery	Li-ion 7.4 V, Rechargeable, Maximum Protection
Battery Operating Time	5 hours
Battery Charging Time	3 hours

Note: System power is designed to work without interruption. It means you can disconnect main power and the system will switch to the internal battery automatically without any delay.

IEC (International Electrotechnical Commission) Classifications	
Type of protection	Class I
Degree of protection	Type BF
Mode of operation	Continuous
Degree of protection against ingress of liquids	Ordinary (IP42)
Recommended methods of sterilization or disinfection	Using a soaked swab with alcohol for the external parts of system for appropriate cleaning instructions.
Degree of safety of application in the presence of a flammable anesthetic	Not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

List of Relevant Standards		
1	IEC 60601-1:2024	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	IEC 60601-1-8:2006	Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
4	ISO 80601-2-55:2018	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
5	IEC 62304:2006	Medical device software - Software life cycle processes
6	ISO 14971:2019	Medical devices - Application of risk management to medical devices

3-2- Alarm signals

3-2-1 Auditory and visual alarm signals

The system is capable of announcing audio and visual alarms to reduce the risk of patient injury during vital signs monitoring. The alarms in this system are categorized into two types: physiological and technical. They are presented in the following tables based on their priority of announcement:

Physiological Alarms		
Priority	**Visual**	**Audible**
High Priority	No Breath	✓
Medium Priority	High $EtCO_2$	✓
	Low $EtCO_2$	✓
	High Respiration Rate	✓
	Low Respiration Rate	✓
	High $FiCO_2$	✓

Technical Alarms		
Priority	**Visual**	**Audible**
High Priority	Low Battery	✓
Medium Priority	Sensor Over Temperature	✓
	Sensor Faulty	✓
	Compensation	✓
	Sensor Disconnected	✓
	Zero In Progress	✓
	Sensor Warming Up	✓
	Zero Required	✓
	CO_2 Out of Range	✓
	Check Airway Adapter	✓
	Check Tubes	✓

System Message		
Priority	**Visual**	**Audible**
NO	Sensor Disabled	×

The alarm indicator flashes red color when a high-priority alarm occurs, and yellow color when a medium-priority alarm occurs. When the alarm terminates, the alarm indicator turns to green color**.**

3-2-2- Sensor alarms

In general, the alarms related to the sensor along with the description of each warning are presented in the following table:

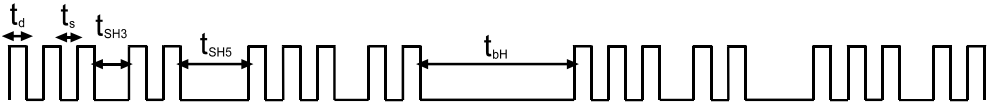
Alarm	Description
Sensor Over Temperature	The sensor is overheated.
Sensor Faulty	The sensor is no longer in service.
Compensation	The sensor needs to receive compensation values in the capnograph settings menu.
Sensor Disabled	The sensor is suspended and needs to be enabled again.
Zero In Progress	Zero-point calibration is in progress.
Sensor Warming Up	The sensor is heating up.
Zero Required	Zero-point calibration is required.
CO_2 Out of Range	The measured CO_2 value is more than 150 mmHg.

3-2-3- Characteristics of auditory alarm signals

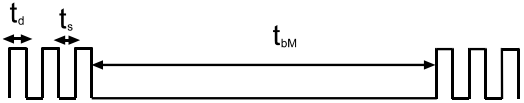
This system auditory alarms are divided into two modes: High Priority and Medium Priority. Accordingly, the values related to the characteristics of the produced audio signal for each priority are as follows**:**

Pulse frequency			700 Hz		
Effective pulse duration (t_d)	High Priority	50 ms	Pulse spacing (t_S)	High Priority	50 ms
	Medium Priority	170 ms		Medium Priority	130 ms
t_{SH3}		150 ms	t_{bH}		10 s
t_{SH5}		550 ms	t_{bM}		20 s

High Priority:



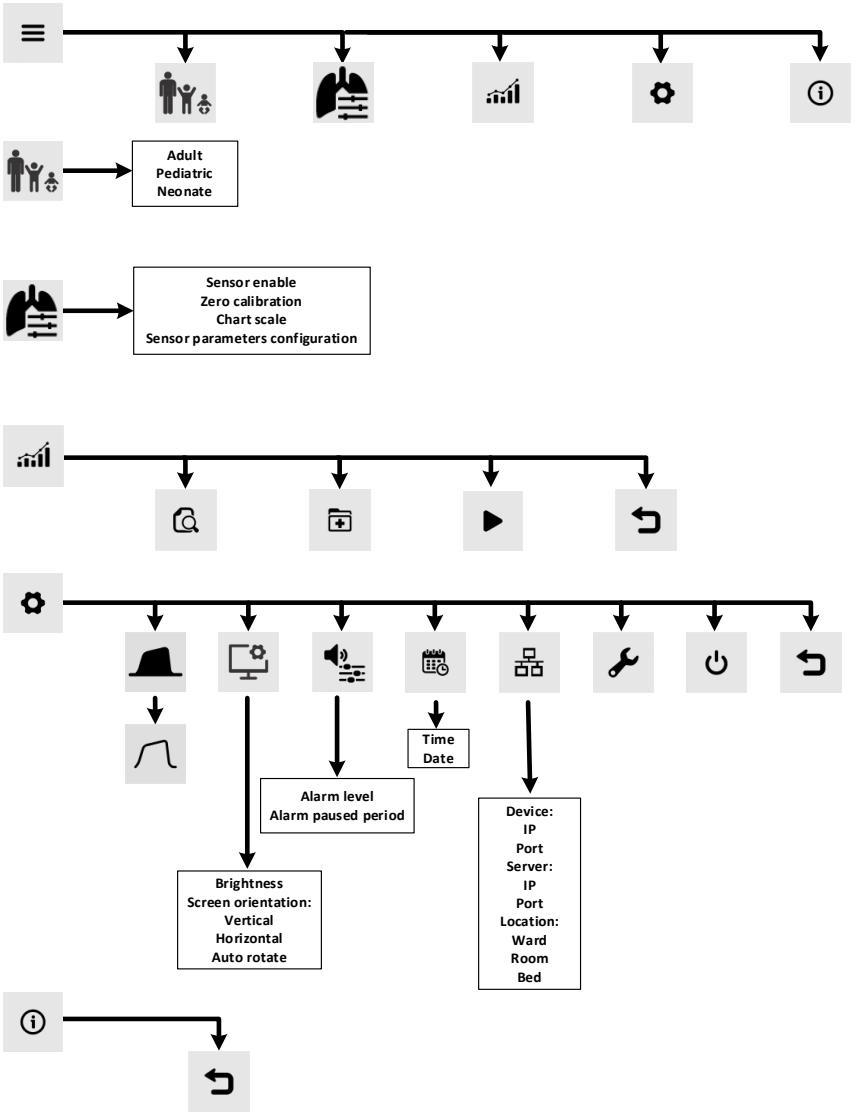
Medium Priority:



The sound pressure level of the auditory alarm signal at a distance of 1 meter from the device is proportional to the percentage of the output sound (adjustable in 10 intervals) in the range of 55 dB to 62 dB**.**

3-3- Menu keys and settings

All the device settings along with the sub-category menus are briefly presented in the figure below.



Warning:

Do not unscrew the device; there is no hardware setting for the user inside the device. For device service, please directly contact Parsian Medical Co.

Attention:

The delivered device does not need calibration. All services related to calibration will be provided by Parsian Medical Co.

4-1- Battery maintenance

If the system on battery mode is not used for a long time, battery may be discharged during transportation or storage. If the battery is not charged for more than a month, recharge it for at least 5 hours before using it again**.**

4-2- Cleaning the device and reusable sensors

To clean the device, use a cotton or sanitary gauze soaked in 70% alcohol, and make sure that the liquid does not leak into the device. Keep the following things in mind when cleaning:

- This device cannot be autoclaved or cleaned with steam.
- Do not immerse the device in washing liquids.
- Solvent detergents can cause damage to the external surfaces of the device.

You can stablish the same method to clean and disinfect sensors. However, when cleaning the sensors, make sure all blood and liquids are completely cleaned, leaving no trace of colored liquid or dirt on the LEDs.

4-3- Repair rules

All repairs must be done by Parsian Medical Co. Other repairer services are only permitted with manufacturer authorization. Otherwise, warranty and after-sales service will not be valid for device.

4-4- Packing and sending the device

Send the device directly to the company at the address provided, or via local authorities.

Address: 1st Floor, No. 3, 8th St., Sabounchi St., Beheshti Ave., Tehran, Iran

Tel: +98-21-88528362,3

Fax: +98-21-88528364

Website: www.parsianmedical.com

Email: info@ parsianmedical.com

Attention:

Please clean the device and send it with the following items.

- **A note providing a description of the observed errors and problems**.
- **Client information, including address, phone number, email address, or postal code**.

4-5- Inaccuracy in measurement

Inaccurate measurement may occur according one of the following conditions:

- The zero-point calibration is not done correctly**.**
- Calibration is done without an adapter**.**
- Gas balance is incorrectly selected in the capnograph settings menu.

- Zero gas in the capnograph settings menu during patient monitoring should be Air. The selection of N_2 is intended for measurements under laboratory conditions.
- Improper operation or incorrect use of the sensor.
- Leakage at the sensor's connection point.
- Obstruction of air tubes.
- Incorrect functioning of sensor filters in Microstream sensors.
- The ACCUCAP911 device works based on the default values of the following parameters. In case of any change in these parameters, there will be interference in the measurement of $EtCO_2$ and $FiCO_2$, and it is necessary to change these values in the capnograph settings menu:

Oxygen: 16%
Anesthetic agent: 0%
Gas temperature: 35 ºC

4-6- Quick troubleshooting

Problem	Cause of occurrence	Troubleshooting instructions
The device does not turn on.	The battery is very low.	Connect the device to the mains and keep it connected for at least 3 hours until it is fully charged.
	The battery needs to be replaced.	Contact Parsian Medical Co.
	The power cable is damaged.	Check the charger using an ohmmeter and replace it if there is a problem.
The battery does not keep the charge and is discharged quickly.	The battery needs to be replaced.	Contact Parsian Medical Co.
Factors are not displayed when the sensor is connected to the patient.	The system is damaged.	Contact Parsian Medical Co.
	The sensor is damaged.	Contact Parsian Medical Co.
	The cable is damaged.	Contact Parsian Medical Co.
When the device is connected to the patient, vital signs are interrupted or not displayed.	There is an obstacle in front of the pipes.	Unblock.
	The moisture filter is saturated.	Changing the filter and connecting pipe and zero-point calibration.
	If the message "Sensor Warming Up" is displayed, the sensor's heating stage is not finished.	Wait until this step is complete.
	If the “Compensation” message is displayed, the sensor cable is disconnected.	Contact Parsian Medical Co.
The sound of the speaker is not heard properly.	There is an obstacle blocking the sound.	Try to remove that obstacle.
	The speaker is broken.	Contact Parsian Medical Co.
Not enough backlight.	The intensity of the backlight needs to be adjusted.	Go to the corresponding menu and change the intensity of the backlight to reach the desired level.
Unable to connect to the network.	The settings of the IP values are not correct.	Go to the relevant menu and check the settings again.

Section 5 – Preventive maintenance

The term "preventive maintenance" refers to a set of activities that are implemented in order to increase the efficiency and postpone repairs. These activities include control, inspection and periodical quantitative and qualitative review of the device, verifying output accuracy through calibration tests usually conducted annually. Additionally, safety reviews are conducted to minimize the risks associated with device defects, ensuring the well-being of both patients and personnel and perform activities such as cleaning, oiling or replacing parts that have problems. With this definition and a cautionary note that the content of this section pertains to the medical engineering department or the maintenance of hospitals and health facilities, the quantitative and qualitative preventive maintenance activities of this device are presented as follows. The recommended intervals for preventive maintenance typically range from six months to one year for calibration**.**

5-1- Quantitative activities

- Check the external part of the device for cleanliness and favorable physical conditions. Make sure that the plastic case is intact, all hardware is available, and there are no signs of liquid spills, contamination, or damage or breakage.
- Ensure that the device is accompanied by the necessary documents**.**
- All labels on the device must be intact and clearly legible**.**
- Make sure that there are all accessories of the device based on the contents of this document.
- Match the glass fuse and their nominal value with the value written next to the fuse base. Then make sure of their correct operation using an ohmmeter.
- Make sure there is a spare for the fuse.
- It is essential to ensure the correctness of the ground connection in the devices. For this purpose, the test has been done by connecting one of the ohmmeter sensors to the applied ground terminal backside of the device and then connecting the other

sensor to the corresponding part of this connection on the ground pin of the device cable and observing the ohmic value of the electrical connection.

- Check all sensor cables along with their protective cover in terms of general condition. Carefully examine the cables to find any breaks on their insulation and their firmness in the connectors at both ends and their non-rotation, and by bending the ends of the cables from their possible inefficiency or by be sure to use an ohmmeter.
- Check all electrical connectors for normal conditions. All electrical pins or connections must be smooth, clean and shiny. Check that the connector is easily installed in its place. If keyed connectors are used, make sure the keyed connection is correct.
- Assure there is enough airway adapter in the warehouse.
- Make sure ON / OFF button functions correctly.
- Make sure the performance of the screen by checking its pixels.
- Make sure that the LEDs on the CAPNOSTAT 5 sensor are clean and that there is no color or blood on them by opening of the sensor.

5-2- Quality activities

- It is possible to measure the accuracy of the RR factor by point-to-point comparison with the vital signs monitor device with the ability to measure the breathing rate per minute by the impedance method. consequently, compare the values displayed by the device with those from this system; they should match.
- Make sure that the capnograph waveform is accurate**.**
- Place the sensor on your airway and activate audio and visual alarms by changing their intervals. Specify that alarms occur within ±1% of the defined limit. By turning off the alarm sound with the key, make sure to reconnect it after 120 seconds. Disconnect the sensor from the breathing path and make sure that the sensor disconnection alarm (No Breath) is activated.

- Check the sound adjustment mechanism in the corresponding menu by establishing one of the conditions for auditory alarms.
- Verify that the alarm limits are reset to the default interval, as specified by the standard, after the device is powered off and then turned it on.
- Verify the battery status of the device after it has been fully charged. Ensure that the device operates on battery power for no less than one hour.
- Ensure that the battery symbol is displayed on the screen when the charger is disconnected from the device while it is in operation.
- Make sure that the red battery symbol is activated on the screen when the battery charge is low. For this purpose, disconnect the power cable from the device and allow the device to operate for a period of time to deplete some the internal battery's power.
- Verify the functionality associated with temporarily deactivating the device's audio alarms by selecting the corresponding option  on the screen.
- Set the time and date from the relevant menu. Turn off the device, disconnect it from the charger, and then turn it back on to ensure that the battery and its electronic circuit are functioning correctly.
- To verify the accuracy of $EtCO_2$ within the intervals specified in the tables this manual, use the methods outlined in the relevant standard (ISO 80601-2-55:2018).

Section 6 – Warranty

6-1- Warranty information

This device is covered by a one-year warranty from the time of delivery, provided by Parsian Medical Co., guaranteeing its performance in all typical medical environments. Please note that batteries are not included in this warranty.

To extend the warranty, the device must be returned to the company again. After undergoing tests and necessary part replacements, the warranty will be extended for an additional year, based on the terms of agreement.

This warranty does not apply to devices that have been improperly used, sustained physical damage, or not been operated in accordance with the conditions of the accompanying documents.

Devices that have been modified, opened, or have been inspected by service personnel other than the employees of Parsian Medical Co. are out of the scope of this warranty.

This warranty does not cover accessories and other devices that are connected to this system (sensors and airway adapter).

This warranty is issued to the buyer by Parsian Medical Co. and supersedes any oral agreements on this matter. It does not cover unforeseen events.

Device and Accessories

No.	Part Name	Presence	No.	Part Name	Presence
1	ACCUCAP911	☐	8	Quick Manual	☐
2	CAPNOSTAT 5 Sensor	☐	9	Wall-mount Bracket	☐
3	LoFlo Sensor	☐	10	Trolley	☐
4	Power Cable	☐	11	USB Cable	☐
5	Sensor Adapter	☐	12	Ethernet Cable	☐
6	User Manual	☐	13	Software Pack	☐

Serial Numbers

No.	Part Name	Serial Number
1	ACCUCAP911	
2	Sensor	

PARSIAN MEDICAL

1st Floor, No. 3, 8th St., Sabounchi St., Beheshti Ave., Tehran, Iran
Tel: (+98 21) 88 52 83 62 - 3 Fax: (+98 21) 88 52 83 64
info@parsianmedical.com www.parsianmedical.com

ACCUCAP 911®