



Multigas Analyzer

AMG-06

User manual

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CONTENT

| | |
|--|-----------|
| 1 DEVICE DESCRIPTION..... | 5 |
| 1.1 INTRODUCTION | 5 |
| 1.1.1 Intended Use and Scope..... | 9 |
| 1.1.2 General Guidance | 9 |
| 1.1.3 Revision History | 11 |
| 1.1.4 Safety Precautions | 11 |
| 1.1.5 Electromagnetic Compatibility..... | 14 |
| 1.1.6 Operation Principle..... | 14 |
| 1.1.7 Basic Technical Characteristics | 14 |
| 1.2 COMPONENTS OF THE DEVICE AND MARKING..... | 19 |
| 1.2.1 Information Display..... | 19 |
| 1.2.2 Water Trap..... | 19 |
| 1.2.3 Sampling Tube | 21 |
| 1.2.4 Exhaust Gas Tube..... | 21 |
| 1.2.5 Power Adapter..... | 22 |
| 1.2.6 Symbols..... | 22 |
| 1.3 INTERFACE DESCRIPTION | 25 |
| 1.3.1 “Monitoring” screen | 27 |
| 1.3.2 “Trends” Screen | 33 |
| 1.3.3 “Alarm log” Screen | 39 |
| 1.3.4 “Settings 1” and “Settings 2” Screens | 42 |
| 1.3.5 “Advanced Settings” Screen..... | 45 |
| 1.3.6 “Wi-Fi settings” Screen..... | 48 |
| 1.3.7 “Patient Information” Screen | 50 |
| 1.3.8 Status Line..... | 52 |
| 1.3.9 Virtual Keyboard..... | 52 |
| 2 PREPARING FOR OPERATION | 54 |
| 2.1 DISINFECTION | 54 |
| 2.2 POWER ON..... | 55 |
| 2.3 ALARM SYSTEM | 56 |
| 3 OPERATION | 65 |
| 3.1 CONNECTION OF THE DEVICE..... | 65 |
| 3.2 THE DEVICE OPERATION | 66 |
| 3.2.1 Test Methods..... | 66 |
| 3.3 ZERO CALIBRATION OF THE DEVICE | 67 |
| 3.4 MAC | 67 |

| | |
|---|-----------|
| 3.5 INTERNAL BATTERY | 68 |
| 3.5.1 Battery Cycling | 70 |
| 4 MAINTENANCE | 72 |
| 5 TROUBLESHOOTING | 73 |
| 6 DELIVERY SET | 75 |
| 7 STORAGE | 77 |
| 8 TRANSPORTATION | 78 |
| 9 DISPOSAL | 79 |
| 10 WARRANTY | 80 |
| 11 CERTIFICATE OF ACCEPTANCE | 83 |
| 12 COMMISSION DATE MARK | 84 |
| 13 MAINTENANCE AND REPAIR DATA | 85 |
| 13.1 Device Maintenance (MA) | 85 |
| 13.2 Device Repair | 85 |
| APPENDIX A. ELECTROMAGNETIC COMPATIBILITY | 86 |
| APPENDIX B. PROTOCOL OF INFORMATION EXCHANGE WITH AN EXTER- NAL MEDICAL INFORMATION SYSTEM | 89 |
| APPENDIX C. INTERFERING GAS AND VAPOR EFFECTS | 90 |
| APPENDIX D. CALCULATION OF THE MAC COEFFICIENT DEPENDING ON THE AGE | 92 |

1 DEVICE DESCRIPTION

1.1 INTRODUCTION

The present user manual applies to the Multigas Analyzer AMG-06 (hereinafter – the device). The manual is intended for trained medical personnel using the device. Appearance of the device is presented in Figure 1.1.



- 1 - touch screen (multicolor TFT-display);
- 2 - water trap;
- 3 - power adapter;
- 4 - sampling tube;
- 5 - "Power" LED indicator
- 6 - "on/off" button and LED indicators;
- 7 - "Bat." LED indicator;
- 8 - exhaust gas tube;
- 9 - marked depending on a distributor: it can be either Sedana Medical or Treaton

Figure 1.1 - Set of the device

The device consists of an information display with 5" TFT-touch screen, button with LED indicators, water trap, sampling tube (or sampling line), exhaust gas tube and power adapter.

At the right-side panel of the device the following connectors are placed:

- Outlet port (marked as "OUT" and including exhaust symbol per EN ISO 80601-2-55);

- Power adapter connector (marked as “Power”);
- RS232 connector (marked as “RS232”).

Device right side panel is shown in Figure 1.2.



- 1 - Outlet port;
- 2 - power adapter connector;
- 3 - RS232 connector.

Figure 1.2 – The device right side panel

A slot for the water trap is placed at the left side panel of the device (Figure 1.3, position 1). The slot for the water trap contains a lock button (Figure 1.3, position 4).

The device is portable and it can be placed on any working surface or suspended and fixed at any surface near patient.

On the rear housing panel, a fastener is placed. The rear panel has special slots to fix the fastener rotation angle (Figure 1.4). The lock button of the fastener swivel unit is located between housing part and fastener (Figure 1.3). The fastener has a shape with circular edges. The fastener

supports the device when it is located on the working surface. Its surface has adhesive legs enabling the device to be fixed securely.

The fastener swivel unit is placed on the rear part of the device.



- 1 - slot for water trap;
- 2 - fastener with swivel unit;
- 3 - lock button of the fastener swivel unit;
- 4 - lock button of water trap.

Figure 1.3 – The device left side panel

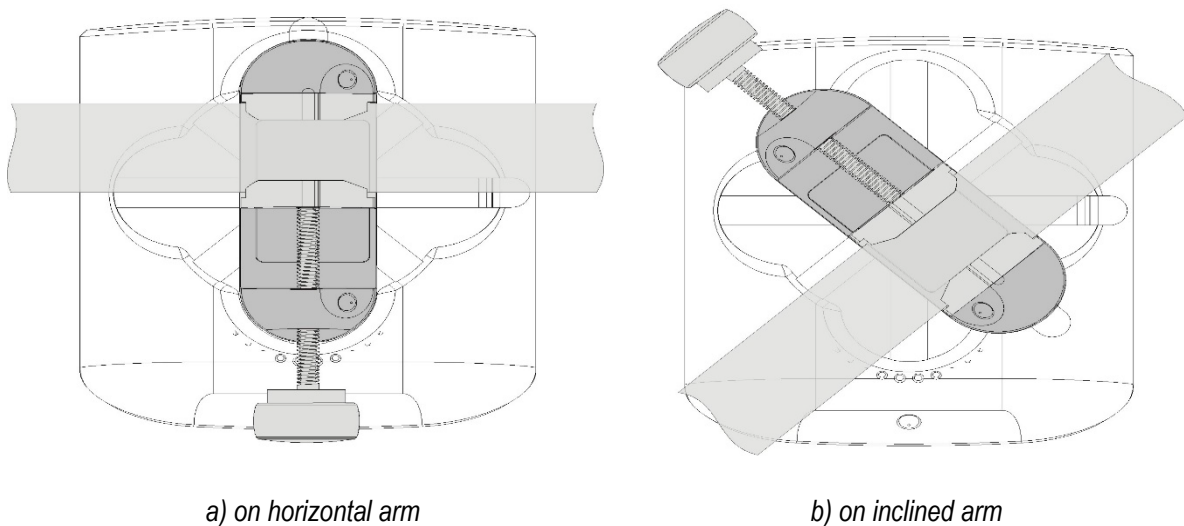
The fastening system provides an optimal positioning on a pole or rail, such as ventilation equipment rails and other hospital mountings. It is possible to turn the fastener and fix the rotation angle, which enables to fix the device on horizontal and vertical surface. The fastener has a grip, which also enables to fix the device on a wide variety of objects. This fastening system enables the device to be tightly fixed and easily removed.

The grip concept is used for fixing the device at table edges and suspending it to bedside objects (Figure 1.5). These two items enable the device to be fixed tightly.



1 - fastener handle; 2 - fastener body; 3 - fastener pin; 4 - fastener pad; 5 - fastener grip.

Figure 1.4 – The device rear panel



a) on horizontal arm

b) on inclined arm

Figure 1.5 – Examples of the device fixation

The first item is motionlessly located on the fastener body, the second one is affixed to the screw-threaded pin, which enables the device to be easily fixed with handle on objects of different shapes and diameters. The handle of the fastener is circular-shaped and has special hollows on

the side face to prevent slippage of fingers.

1.1.1 Intended Use and Scope

The device is intended for continuous non-invasive monitoring of CO₂, isoflurane (ISO), sevoflurane (SEV), desflurane (DES) concentration in inspired (FiCO₂, FiDES, FiISO, FiSEV) and expired (EtCO₂, EtDES, EtISO, EtSEV) gas without automatic identification of anaesthetic, and also for determining patient's respiration rate (RSP) and apnea, MAC index, and measuring atmospheric pressure under the conditions of operation rooms and wards when providing anaesthetic support.

Scope: anaesthesiology, intensive care during postoperative period, prolonged sedation, resuscitation, transportation of patients inside of professional healthcare facilities.

The device is intended for use with patients above the age of 3 years.

The device does not contain any major contraindications.



1.1.2 General Guidance

The present user manual is an integral part of the device and a part of the delivery set.

User manuals in all languages present in the interface of the device and additional user documentation are available at <http://www.treat-on.com/>.

Carefully read this entire manual and the corresponding site section of Triton Electronic Systems Ltd. before using the device. Remember that mishandling can lead to device malfunction or even its failure.

The following symbols are used in the manual:

| | |
|---|--|
|  | <p><u>PROHIBITION</u> Violation of the established restrictions or non-compliance with the requirements regarding the use of materials, methods and techniques for handling the device may lead to a violation of safety measures</p> |
|  | <p><u>WARNING</u> Identification of a clear danger to a person performing certain actions, or the risk of damage to the device.</p> |



CAUTION

Focusing the attention of personnel to methods and techniques that must be followed accurately to avoid errors during use and repair of the product or when increased caution is required in handling the device or materials.

In case of unstable operation of the device, doubts about correctness of its operation or accuracy of measurements or in case of malfunctions, please read carefully appropriate sections of the manual, and also refer to the list of fault conditions and their troubleshooting (see section 5).

The device performs a continuous self-test procedure after it is switched on, as well within operation process.



CAUTION

Due to continuing improvement of technical and performance characteristics, device reliability, design, electrical circuit and software are subject to change without notice. Therefore, insignificant difference between your device and device described in the manual is possible.

CAUTION

The manufacturer is not responsible for failure of the device if instructions listed in the user manual are not followed.

Triton Electronic Systems Ltd. is responsible for device operation and its characteristics, only if:

- electric wiring in a relevant room complies with the requirements of the appropriate standards;
- the device is used in accordance with the user manual;
- after-sales service and repairs are performed by persons with required qualification and instruments, and authorized by Triton Electronic Systems Ltd.

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The expected service life of the device is 5 years.

To ensure the device operational reliability and to increase its service life, it is NECESSARY:

- to protect the device, especially surface of the display, from falling and damages;
- after transportation or storage at below-zero temperature, to hold the device at temperature corresponding to operating conditions for at least 12 hours before switching on;
- to perform cycling (charge, then discharge) of the built-in battery regularly (p. 3.5.1), to avoid its deep discharge and long stay in a discharged condition;
- not to apply force to cable at disinfection and its disconnection from device;
- to keep cables and modules away from wheels of trolleys and other heavy items in order


to avoid its damage and failure;

- to avoid liquid ingress into the device and to connector pins during disinfection (module disinfection by immersion method is forbidden).

1.1.3 Revision History

Each manual edition has its number and date indicated on the front page. Number and date are changed in case of significant changes in the manual. Insignificant changes and corrections do not entail a change of date and edition number.

1.1.4 Safety Precautions

| | |
|---|---|
|  | <p><u>WARNING</u> In case of any emergency situation during the operation (fire, short circuit, etc.), immediately disconnect the device from a patient and continue monitoring by another device.</p> |
| | <p><u>WARNING</u> Do not pull or bend power cable of the device. Failure to follow these instructions may cause cable discontinuity, short circuit, skin burn of a patient from the device temperature increase due to short circuit of the cable, and measurement cannot be performed. If the device is broken, replace it with a new one.</p> |
| | <p><u>WARNING</u> Do not let a patient bite the power cable and sampling tube. This can cause device malfunction and harm a patient.</p> |
| | <p><u>WARNING</u> Do not carry an operating device with a full water trap, and do not remove it while the device is operating in order to prevent liquid getting into the measuring cell.</p> |
| | <p><u>WARNING</u> Do not turn the device even with a partially filled water trap. This can cause device malfunction.</p> |




CAUTION
 Carefully read the present user manual.

CAUTION
 Do not diagnose a patient based only on a data acquired with the device. Overall judgment must be performed by a physician who understands the features, limitations and characteristics of the device.

CAUTION

Usage of the device is allowed for qualified medical personnel after reading and understanding this user manual.

| | |
|---|---|
|  | <p><u>PROHIBITION</u> Do not use the device in the operating conditions of the nuclear magnetic resonance equipment.</p> |
| | <p><u>PROHIBITION</u> Avoid a liquid ingress into the housing and display of the device during operation.</p> |



CAUTION

The operation of the device may be affected by equipment located nearby. Before use, check that the device operates normally with other equipment.

CAUTION

The device can be used with high-frequency electrosurgical devices. For detailed information on operation conditions refer to the user manual of an electrosurgical device.

CAUTION

The device is designed only for visual monitoring and automatic registration of patient's physiological parameters and does not relieve medical personnel of the responsibility of continuous physical supervision over a patient. The device is intended for use under the direct supervision of medical personnel.

CAUTION

The measured value may be incorrect when the operating temperature changes greatly.

CAUTION

Empty water trap's reservoir, if it is filled in half.

CAUTION

Dispose accumulated fluids and sampled gases according to user national standards and user facility's guidelines for waste disposal.

CAUTION

Nitrous oxide must not be present in the gas mixture.

CAUTION

During operation of the device, some gases in the mixture can lead to measurement error, see Appendix C.

CAUTION

Recommended separation distances between portable and mobile radio frequency (RF) communications equipment and the device are stated in Appendix A.

CAUTION

The device, sampling tube, exhaust gas tube, water trap and packaging are made with no natural rubber latex.

After transportation or storage at below-zero temperature, it is necessary to hold the device at temperature corresponding to operating conditions in a package for at least 12 hours before switching on.

During operation **it is forbidden:**

- to remove the cover of the device without disconnecting the device from mains supply;
- to disinfect the device while it is in switched-on state (power adapter must be disconnected from the wall socket);
- to clean, sterilize or re-use the single-use accessories. This can cause equipment malfunction and potentially harm a patient.
- to modify the device without the permission of the manufacturer.
- to use the device in operating conditions of the nuclear magnetic resonance equipment.

During operation **remember:**

- the device is designed only for displaying patient's physiological parameters and does not exempt medical personnel from a responsibility of continuous physical observation over patient;
- the device is intended for use under the direct supervision of medical personnel;
- in order to provide patient's safety, it is strongly recommended not to disable audible alarm;
- if the device is installed by screws, it is necessary to provide its secure fixing to prevent it from dropping. Do not apply excessive force when connecting or disconnecting the cables;
- the barometric pressure is compensated by the device during measurements. An integrated atmospheric pressure sensor is used for it;
- the packaging materials from accessories, including packaging from disposable accessories, shall be disposed according to user national standards and user facility's guidelines for disposal waste.

The device is class II medical electrical equipment while powered from external alternative current source.

1.1.5 Electromagnetic Compatibility



CAUTION

During operation it is strongly recommended to use the device in the specified electromagnetic environment, see Appendix A. Otherwise, the maximum performance cannot be guaranteed due to electromagnetic disturbances.

During operation, it is necessary to use the power adapter supplied with the device.

1.1.6 Operation Principle

The Multigas Analyzer AMG-06 is a side-stream gas analyzer, where the portion of gas from the patient breathing circuit is transferred to the device for analysis through the sampling tube. The device is connected to a patient breathing circuit via gas monitor port or adapter with Luer Lock connector (T-piece or Y-piece).

The device enables continuous measurement of CO₂, desflurane (DES), isoflurane (ISO), sevoflurane (SEV) concentration in the patient's airway by infrared spectrophotometry. The method is based on absorption measurements of infrared light with wavelengths 4,2 µm, 7,85 µm and 8,3 µm calculated on the basis of measured amount of light transmitted through the gas to the sensor. The concentration of CO₂ and anaesthetic is calculated from the partial pressure using atmospheric pressure.

The device with a source of infrared emitter and a photodetector is mounting on the measuring cell. The cell has two windows, transparent to infrared light. Through these windows, the light from the infrared source passes through the measured gas mixture and enters the photodetector of the sensor. Thus, the device measures the degree of absorption of infrared rays during its passage through the gas stream.

End-tidal (expired) gas concentration is calculated using software based on the analysis of capnogram graph.

1.1.7 Basic Technical Characteristics

Basic technical characteristics of the device are presented in Table 1.

Table 1 Operating parameters

| № | Parameter | Value (description) |
|---|------------------------|---------------------|
| | Main parameters | |

| № | Parameter | Value (description) |
|---|---|--|
| 1 | Measured gases | CO ₂ , and anaesthetic agents alternately SEV or DES or ISO. |
| 2 | Measurement parameters | FiCO ₂ , FiDES, FiISO, FiSEV, EtCO ₂ , EtDES, EtISO, EtSEV, RSP Inspired and expired concentration of CO ₂ and anaesthetic agent, respiration rate |
| 3 | Warm-up time | ISO accuracy within 45 s (warming-up time) Full accuracy within 10 min (in normal mode) |
| 4 | Operation principle | Non-dispersive infrared (NDIR) |
| 5 | Measurement range CO ₂ DES ISO SEV | 0-15.0 Vol% or kPa (resolution 0.1) 0-17.0 Vol% (resolution 0.1) 0-5.0 Vol% (resolution 0.1) 0-7.0 Vol% (resolution 0.1) |
| 6 | Accuracy CO ₂ DES ISO SEV | ± (0.43 Vol% + 8 Vol% of gas level) ± (0.2 Vol% + 15 Vol% of gas level) ± (0.2 Vol% + 15 Vol% of gas level) ± (0.2 Vol% + 15 Vol% of gas level) |
| 7 | Gas sampling flow rate (flow rate) range Accuracy of gas flow rate | 50-250 ml/min ±10 ml/min (or ±10% whichever is greater) |

| № | Parameter | Value (description) |
|------------|--|---------------------|
| 8 | Response time Adult version of sampling tube 250 cm, gas flow rate 250 ml/min Neonate version of sampling tube 250 cm, gas flow rate 120 ml/min | 2.5 s |
| 9 | Rise time (0,1 – 0,9 Ames) Adult version of sampling tube 250 cm, gas flow rate 250 ml/min Neonate version of sampling tube 250 cm, gas flow rate 120 ml/min | 0.5 s |
| 10 | Max respiration rate with influence of flow rate when CO ₂ and anaesthetics save accuracy (neonate version of water trap) | |
| | 50 ml/min | maximum 40 BPM |
| | 70 ml/min | maximum 50 BPM |
| | 90 ml/min | maximum 60 BPM |
| | 110-120 ml/min | maximum 65 BPM |
| | Max respiration rate with influence of flow rate when CO ₂ and anaesthetics save accuracy (adult version of water trap) | |
| | 120 ml/min | maximum 60 BPM |
| | 130 ml/min | maximum 65 BPM |
| | 140 ml/min | maximum 70 BPM |
| | 150 ml/min | maximum 75 BPM |
| 250 ml/min | maximum 100 BPM | |

| № | Parameter | Value (description) |
|---|---|--|
| 11 | Respiration rate range Accuracy respiration rate | 0 – 160 breath per minute (BPM) ±2 BPM |
| 12 | Calibration | Available |
| 13 | Internal memory capacity | 72 hours |
| 14 | Built-in battery operation time | 2 hour |
| 15 | Normal mode setup time | 45 s |
| 16 | Dimensions | 170 x 155 x 135 mm |
| 17 | Weight, maximum | 1.5 kg |
| <p>Mains parameters</p> | | |
| 18 | Mains power supply | 100-240V, 50/60 Hz |
| 19 | Maximum power consumption | 35 VA |
| 20 | Built-in battery | 2000 mA*h, Ni-Mh, 6 V |
| <p>Operating conditions</p> | | |
| 21 | Ambient air temperature | from 10 to 35 °C |
| 22 | Relative humidity | 10–90 % (at the air temperature of 25 °C). |
| <p>Storage conditions</p> | | |
| 23 | Ambient air temperature | from 5 to 40 °C |
| 24 | Relative humidity | not over 80 % (at the air temperature 25 °C) |
| <p>Transportation conditions</p> | | |
| 25 | Ambient air temperature | from -50 to 50 °C |
| 26 | Relative humidity | not over 80 % (at the air temperature 25 °C) |
| <p>Standards</p> | | |

| № | Parameter | Value (description) |
|----|-----------|--|
| 27 | | <ul style="list-style-type: none"> • Concerning safety, the device complies with EN 60601-1, EN ISO 80601-2-55. • The device is classified as class II ME equipment energized from an external electrical power source; internally powered ME equipment energized from a built-in battery; the water trap and sampling tube (neonate and adult versions), and also exhaust gas tube should be subject to the requirements for the type B applied parts according to EN 60601-1 and EN ISO 80601-2-55. • The degree of protection against harmful ingress of water and particulate matter is IP21. • Concerning electromagnetic compatibility (EMC), the device meets the requirements of IEC 60601-1-2. The device is intended for use in the electromagnetic environment specified in Appendix A. |
| | | <p>*Note: The CO₂, DES, ISO, SEV measurement accuracy can be decreased due to following factors:</p> <ul style="list-style-type: none"> • mechanical damage of the device; • cyclical pressure of up to 10 kPa (100 cmH₂O); • leaks or internal venting of sampled gas. <p>There is no drift in CO₂, DES, ISO, SEV measuring accuracy within at least 6 hours.</p> <p>It is allowed to increase permissible absolute deviations of measurements by 3 times until the full accuracy of measurements is established.</p> <p>The device is powered on correctly if the message “Meas. module warming-up” in the status line and graph state is appeared. Normal mode starts with ISO accuracy within 45 seconds after the “Meas. module warming-up” message.</p> |

1.2 COMPONENTS OF THE DEVICE AND MARKING



CAUTION

After transportation or storage at below-zero temperature, it is necessary to hold the device at room temperature in the package for at least 12 hours before switching on.

The device consists of an information display with TFT-touch screen, button with led indicators, water trap, sampling tube, exhaust gas tube, power adapter.

After unpacking the device, it is necessary to examine all units carefully to be sure that there is no visible mechanical damage or moisture. Carefully remove protective film from the screen surface and wipe it with soft clean cotton cloth.

Software version:

- 1) Version of the indication module - 00.00.XX
- 2) Version of the measurement module - 03.04.XX
- 3) Version of the battery charger microcontroller - 03.02.XX

Where XX is a software subversion, which can be revised with insignificant changes.

A more detailed position of the version is given in fig. 1.30.

1.2.1 Information Display



CAUTION

The display surface shall be protected from mechanical damages in order to avoid surface roughness, scratches and display crack.

The device is controlled using the touch screen (Figure 1.1, position 1). Press touch buttons to change the corresponding information window or the registered parameter. More detailed information on device control by touch screen is given in further sections.

1.2.2 Water Trap



CAUTION

Carefully read the instruction for use supplied with the water trap before use.

CAUTION

No parts of the water trap are intended to be cleaned.

The water trap (Figure 1.1, position 2) protects the device from the humidity, secretions, and

bacterial contamination.

- To install the water trap, align it with the slot (Figure 1.3, position 1) and push gently into place. Make sure that locking mechanism is fully engaged by pulling the water trap, which should be firmly seated.
- To remove the water trap, put the lock button (Figure 1.3, position 4) in the upper position and pull the water trap from the slot.
- To empty the water trap, twist and pull the container relative to the filter housing. Empty the container and re-install the water trap as shown in Figure 1.6.

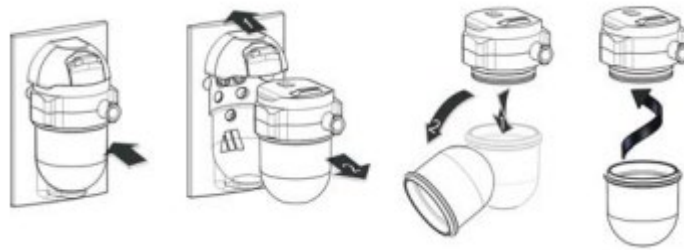


Figure 1.6 – Emptying of a water trap

A water trap has two versions:

- Adult (color-less);
- Neonate (blue center-piece including the Luer Lock connector).

Maximum emptying interval for adult version of a water trap during normal use (operating temperature 23°C, patient respiration gas 37° and 100% RH) is 17 hours at sample flow rate 200 ml/min or 26 hours at flow rate 120 ml/min.

Maximum emptying interval for neonate version of a water trap during normal use (operating temperature 23°C, patient respiration gas 37° and 100% RH) is 26 hours at sample flow rate 120 ml/min or 45 hours at flow rate 70 ml/min.

The version of the water trap is chosen depending on an age group of a patient and necessary flow rate (please refer to table 1, p. 10).

Replace the water trap every month or more often if necessary.

Handle the contents of the water trap as it would be handled any bodily liquids.

For more details concerning application instructions, please refer to the instruction for use of the water trap.

1.2.3 Sampling Tube



PROHIBITION

Do not use other tubes, e.g. IV lines, as it could result in patient harm.
Do not use the sampling tube with flammable anaesthetic agents.



CAUTION

Use only color-less «Adult» version of the sampling tube for «Adult» version of the water trap.

CAUTION

Use only blue «Neonate» version of the sampling tube for «Neonate» version of the water trap.

CAUTION

Carefully read the instruction for use supplied with the sampling tube before use.

The sampling tube (Figure 1.1, position 4) is intended to sample the gas probe from the patient breathing circuit. The sampling tube is a single-use article and shall be properly disposed after each use.

Connect one side of the sampling tube to the inlet port on the water trap. The other side shall be connected to the gas monitor port of the patient breathing circuit or adapter with Luer Lock connector (T-piece or Y-piece).

Check the sampling tube before the connection. It must be dry and clean.

For more details concerning application instructions, please refer to the instruction for use of the sampling tube.

1.2.4 Exhaust Gas Tube

The exhaust gas tube (Figure 1.1, position 8) is intended to remove the gases after analysis in the device. The exhaust gas tube is a single-use article and shall be properly disposed after each use.

The exhaust gas tube shall be connected to the outlet port of the device (Figure 1.2, position 1) from one side and scavenging gas filter from the other side. Refer to instructions for use of the scavenging gas system and filter.

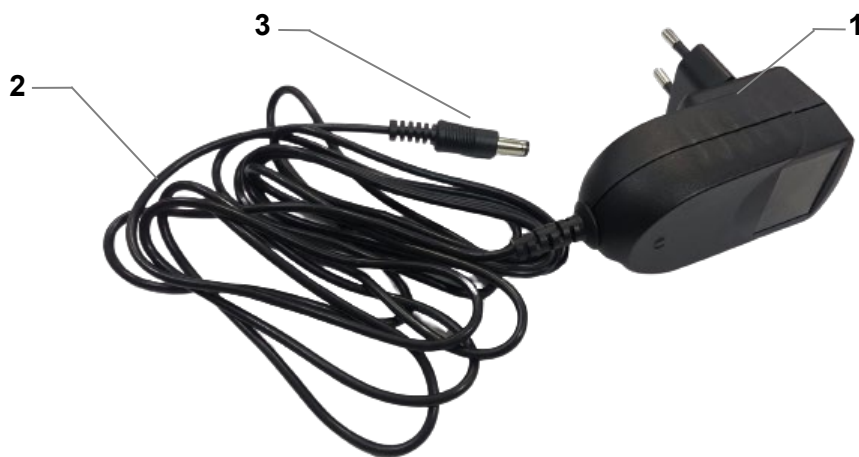
For more details concerning application instructions, please refer to the instruction for use of the exhaust gas tube.

1.2.5 Power Adapter

The device power system enables the device to operate in wide range of mains voltage (100 – 240) V. In absence of alternative current source, the device will turn automatically to operation from battery (p. 3.5).

The device has a power adapter that enables operation from mains power (Figure 1.7).

Connection of the power adapter to the mains power is carried out by the plug installed on the body of power adapter. Connection of the power adapter to the device is carried out by connector (position 3) on a power cable.





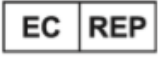

























- 1 – body of power adapter;
- 2 – power cable;
- 3 – connector for electronic unit.




Figure 1.7 – Power adapter

1.2.6 Symbols

| Symbols on device housing | |
|----------------------------------|--|
| | Refer to the accompanying documents! |
| | ON/OFF button |
| Power | Power led indicator of ON/OFF button |
| Bat. | Battery led indicator of ON/OFF button |

| | |
|---|--|
|  | Class II medical electrical equipment energized from an external electrical power source |
| Power | Power adapter connector on the right panel |
| SN | Serial Number |
|  | Mark of Conformity to European Medical Device Directive* |
| UDI | Unique device identification with bar code and number |
|  | Date of manufacturing* |
|  | Manufacturer* |
|  | Authorized representative in EU* |
| IP21 | Type of enclosure protection from ingress of water and solid particles |
|  | Product must be disposed in accordance with the WEEE directive (Directive 2012/19/EU) |
| OUT  | Output symbol for the exhaust gas tube |
| IN  | Input symbol for the sampling tube |
| RS232 | Symbol for the RS232 interface connector |
| Treaton | Treaton marking** |
|  | Sedana Medical marking** |
| Importer and distributor | Information about a distributor |
|  | Symbol for locking the water trap |
| Symbols on interface | |

| | |
|---|---|
|  | Sound alarm pause button (inactive state) |
|  | Sound alarm pause button (active state) |
|  | Sound alarm off icon |
|  | Sound alarm pause icon |
|  | Neonatal water trap |
|  | "Monitoring" tab |
|  | "Trend/Alarm log" tab |
|  | "Settings (1 and 2)" tab |
|  | "Advanced settings" tab |
|  | Battery charging process |
|  | The battery charge level is about 100 % |
|  | The battery charge level is about 50 % |
|  | The residual battery charge is less than 20 % |
|  | Left scroll button of alarms and events field |
|  | Right scroll button of alarms and events field |
|  | Button to change the setting parameter (increase) |
|  | Button to change the setting parameter (decrease) |
|  | Wi-Fi network connection status and communication with external medical information systems |

| | |
|--|---|
| RS | Connection of the device by the RS232 interface |
| Designations on interface | |
| MIS | External medical information system or personal computer with the appropriate software that provides interaction over the information exchange protocol |
| Symbols on accessories | |
| REF | Catalogue number |
| LOT | Batch code |
|  | Do not reuse |
|  | Symbol of not applicability to neonate patients |
|  | Symbol of applicability to neonate patients |

* also applicable for accessories

** depends on a distributor

1.3 INTERFACE DESCRIPTION



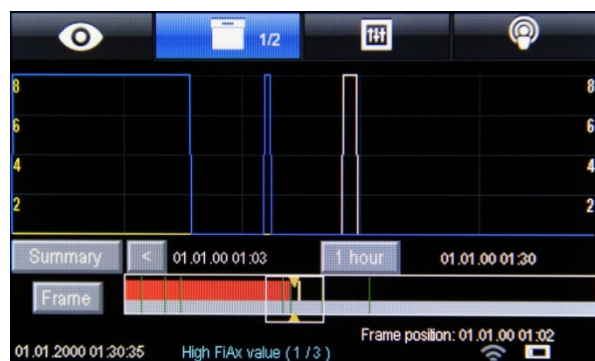
CAUTION

When activating desired operating mode, the corresponding tab is displayed in active (blue) color.

The device has eight screens: “Monitoring”, “Trends”, “Alarm log”, “Settings 1”, “Settings 2”, “Advanced settings”, “Patient information”, “Wi-Fi settings” (Figure 1.8):



a) Monitoring



b) Trends



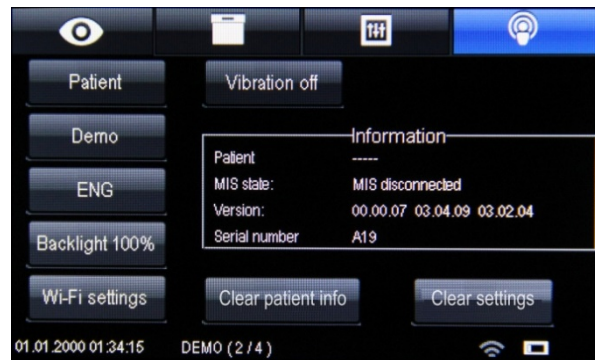
c) Alarm log



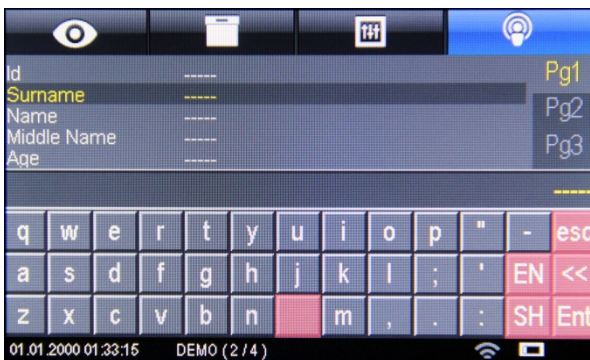
d) Settings1



i) Settings 2



f) Advanced settings



g) Patient information



h) Wi-Fi settings

Figure 1.8 – The device interface

“Monitoring” is the default screen when the device is switched on.

Switching between the screens is performed by pressing the mode switching buttons (hereinafter - “tabs”) at the top of the device screen:

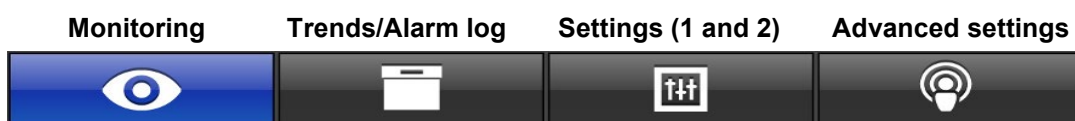


Figure 1.9 – Tabs panel

A single tap of “Trends/Alarm log” button turns on the “Trends” screen. Double tap of

“Trends/Alarm log” turns on the “Alarm log” screen.

A single tap of “Settings (1 and 2)” button turns on the “Settings 1” screen.

A double tap of “Settings (1 and 2)” button turns on the “Settings 2” screen.

1.3.1 “Monitoring” screen

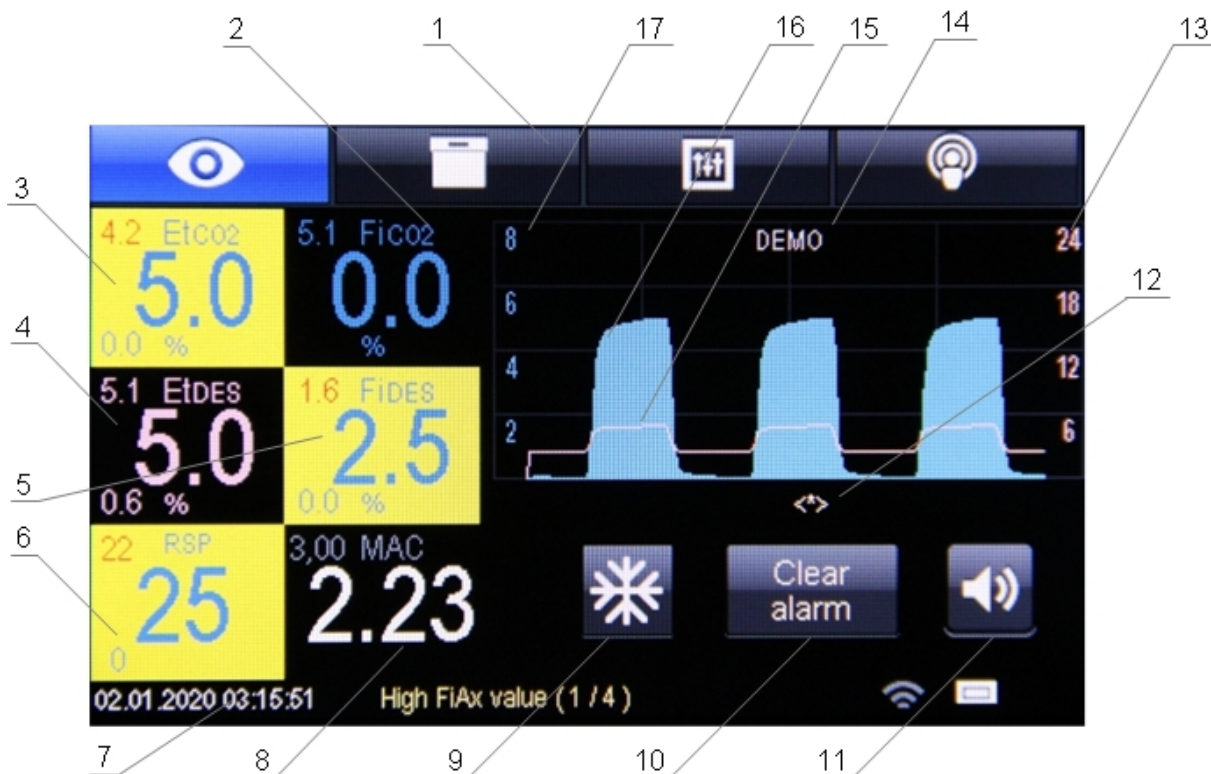
“Monitoring” is the default screen when the device is switched on. Pressing the “Monitoring” button enables to enter the “Monitoring” screen and see the corresponding information (according to Figure 1.10 and preset settings). “Monitoring” screen shown in Figure 1.10 displays all available parameter windows (if checkbox “Show FiCO₂, FiAx” in the “Settings 2” screen is checked).

As a default, the “Monitoring” screen does not display FiCO₂, FiAx, and the checkbox “Show FiCO₂, FiAx” in “Settings 2” screen is unchecked after the device switched on (Figure 1.11).

Parameter windows have one logical structure; its detailed description is shown in Figure 1.12. FiCO₂, MAC windows do not contain low limit and RSP, MAC windows do not display measurement units, because these parameters have one measurement unit.

For more information about MAC, see the section 3.4 “MAC”.

Note: *FiAx value will be frozen when apnea is detected.*



- 1 - Tabs panel;
- 2 - FiCO₂ window (description of parameter windows at Figure 1.11);

- 3 - EtCO₂ window;
- 4 - EtAx window (EtAx cases: EtIso, EtSev, EtDes);
- 5 - FiAx window (FiAx cases: FiIso, FiSev, FiDes);
- 6 - RSP window;
- 7 - Status line;
- 8 - MAC window;
- 9 - Freeze button;
- 10 - Clear alarm button (clear alarm apnea and clear occlusion state);
- 11 - Alarm sound off;
- 12 - ISO accuracy symbol;
- 13 - Anaesthetic graph scale;
- 14 - Graph state;
- 15 - Anaesthetic graph;
- 16 - CO₂ graph;
- 17 - CO₂ graph scale.

Figure 1.10 – “Monitoring” screen

Measurement units of EtCO₂, FiCO₂, EtAx, FiAx parameter windows can be changed in “Settings 1” screen. In case the value parameter window is out of preset limits, the parameter window background will blink red or yellow (according to an alarm level from section 2.3 «Alarm system»).



Figure 1.11 – “Monitoring” screen (default screen without FiCO₂, FiAx)



- 1 - *parameter title;*
- 2 - *high limit;*
- 3 - *parameter value;*
- 4 - *low limit;*
- 5 - *measurement unit;*
- 6 - *parameter window background.*

Figure 1.12 – Parameter window

Color of highlighted parameter on the yellow background:

- parameter title – blue;
- normal limit – blue;
- alarm limit – red;
- measurement unit – blue.

Color of the highlighted parameter on the red background (only apnea, when respiration rate is zero during set apnea time in the “Settings 1 screen”):

- parameter title – blue;
- normal limit – blue;
- alarm limit – white;
- measurement unit – blue.

Two ways of highlighted blinked background are show in Figure 1.12.

For more information about the status line, refer to section 1.3.8 “Status line”.

The freeze button is needed only for graph freeze. First touch of the freeze button stops graph update. Second touch of the freeze button re-starts graph update.

The clear alarm button is needed to clear alarm for apnea and clear occlusion state. The alarm sound off button is needed to pause a sound alarm for 2 minute. After pressing this button,

its pictogram will be changed in case the alarm sound is off.

The ISO accuracy symbol “<*>” appears on the screen if the device has ISO accuracy. When the device has full accuracy, this symbol is hidden. The ISO accuracy symbol also appears during zero calibration.

The graph window contains CO₂ filled graph, anaesthetic line graph and scales for CO₂ and anaesthetic. Also the graph window contains grids and state. The CO₂ filled graph and scale always have blue color. The anaesthetic line graph and scale have the same colors as elements at not highlighted parameter window:

- Isoflurane – purple;
- Sevoflurane – yellow;
- Desflurane – pink.

If the “Show graph value” checkbox on the “Settings 2” screen is checked, a user may see a detailed information about the current graph value of CO₂ and anaesthetic.

The graph window enables a user to set amplitude of CO₂ after pressing the graph window:

- Amplitude 1 – CO₂ max value 8%, 60 mmHg (according to measurement unit).
- Amplitude 2 – CO₂ max value 16%, 120 mmHg (according to measurement unit).

Amplitude setting in graph menu is shown in Figure 1.13.



Figure 1.13– Graph menu, Amplitude

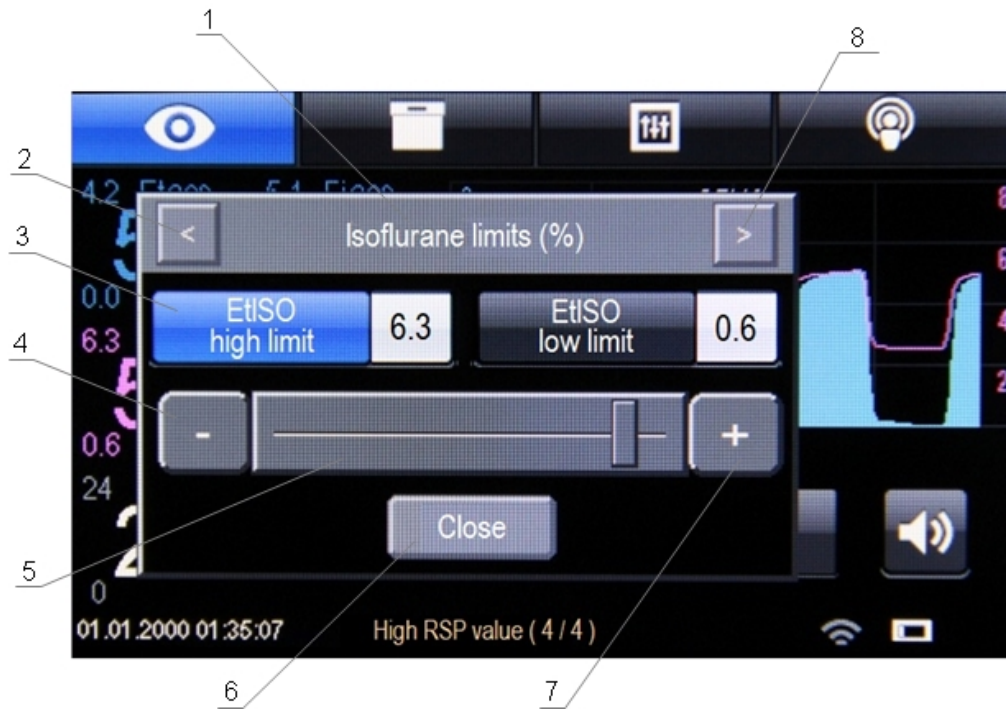
Graph window enables setting a sweep speed (mm/s) after pressing the graph window: 8, 7, 6, 5, 4, 3. Sweep speed setting in graph menu is shown in Figure 1.14.



Figure 1.14 – Graph menu, Sweep speed

Sweep speed also may be set in the “Setting 2” screen.

The parameter windows, except MAC, enable to set limits after pressing the parameter window. The limits menu is shown in Figure 1.15. For parameter limit, it is necessary to press the limit button for selection (selection with blue color) and change limit value by slider moving or pressing “+” or “-” buttons.



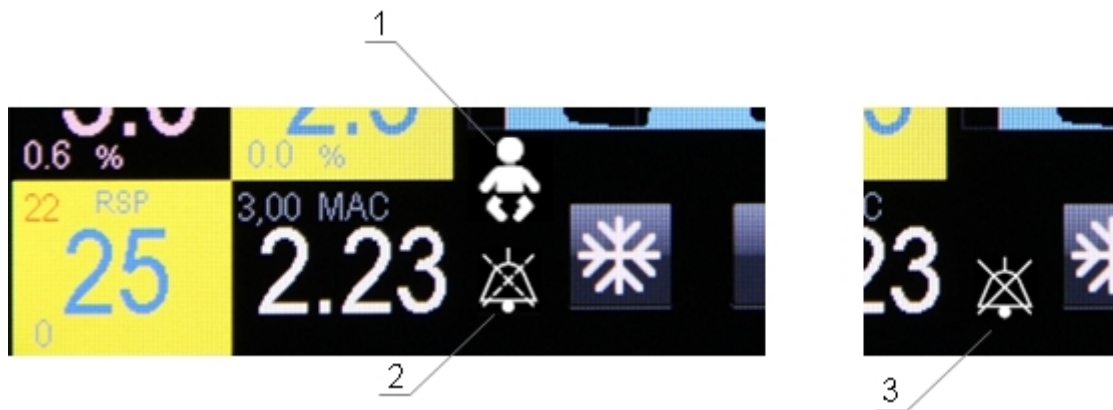
- 1 - title of limits menu;
- 2 - scroll left button;
- 3 - limit button;
- 4 - “-” button to decrement the value;
- 5 - slider;
- 6 - “close” button;
- 7 - “+” button to increment the value;
- 8 - scroll right button.

Figure 1.15 – Limits menu

The limits menu enables to scroll all parameters displayed on the current screen with left and right scroll buttons in circle logic. The title of the limits menu contains parameter name and measurement unit. The “Close” button is intended to close limits menu.

Additional icons are intended to display a pause of an alarm sound lasting for 2 minutes, that an alarm sound is off, and a neonatal water trap connection. The icons are shown in Figure 1.16. The alarm sound off icon is shown in case the sound volume is set to zero in the “Settings 2” screen. Volume of less than 30% does not influence the following alarms:

- High FiCO₂ value;
- Apnea.



- 1 - neonatal water trap icon;
- 2 - alarm sound pause icon;
- 3 - alarm sound off icon.

Figure 1.16 – Additional icons

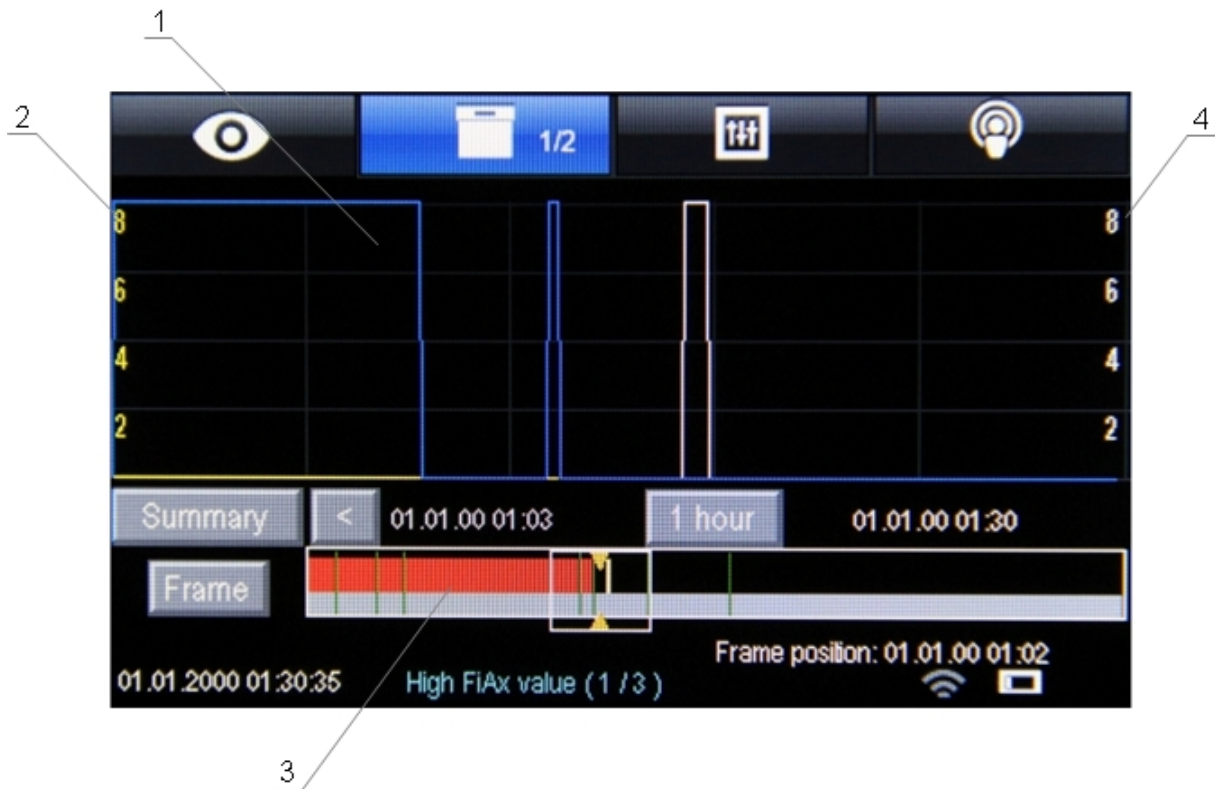
For patient safety, the high FiCO₂ value and the apnea alarm have 30% volume level of an alarm sound if volume is less than 30%. The pause of an alarm sound lasting for 2 minutes does not influence all alarms. The alarm sound off icon is shown only if zero sound volume coincides with the pause of an alarm sound lasting for 2 minutes.

The neonatal water trap icon is shown when a neonatal water trap is connected to the device. The neonatal water trap technical event is saved in the alarm log when the device is switched on or the water trap is replaced or disconnected and connected again.

1.3.2 “Trends” Screen

The “Trends” screen is intended for reviewing stored trends of monitored parameters. Press on the “Trends” tab to enter the “Trends” screen, then corresponding information according to Figure 1.17 and preset settings appears on the screen.

Trends are the data about monitored parameters of a patient, recorded over a certain period of time and displayed in a graphical form to represent the picture of a patient conditions monitored over time. The data recorded with the device for monitored parameters (FiCO₂, EtCO₂, FiAx, EtAx) are automatically stored in its non-volatile memory. A trend starts at the moment when the device is switched on, and finishes at the moment of its switching off. The trends are provided with time labels. When the trend memory is full, the previous data are deleted based on a circle logic. Thus, during continuous operation of the device over 72 hours, the recorded data are always stored in the device’s memory for at least the last 72 hours of the device operation.



- 1 - Trends graph window;
- 2 - scale (yellow) of CO₂ trends (FiCO₂, EtCO₂);
- 3 - navigation panel;
- 4 - scale (white) of anaesthetic trends (FiAx, EtAx).

Figure 1.17 – “Trends” screen

Trends graph window contains grid lines, scales and displays the following trends graph lines:

- FiCO₂ – yellow color;
- EtCO₂ – white color;
- FiAx – red color;
- EtAx – blue color.

The trends graph window displays a frame time period and draws trends which the frame contains at present. The trends graph window supports filter setting to hide and draw graphs as shown in Figure 1.18. The trends graph enables to set amplitude of CO₂ after pressing the trends graph window:

- Amplitude 1 – CO₂ max value 8%, 60 mmHg (according to measurement unit).
- Amplitude 2 – CO₂ max value 16%, 120 mmHg (according to measurement unit).

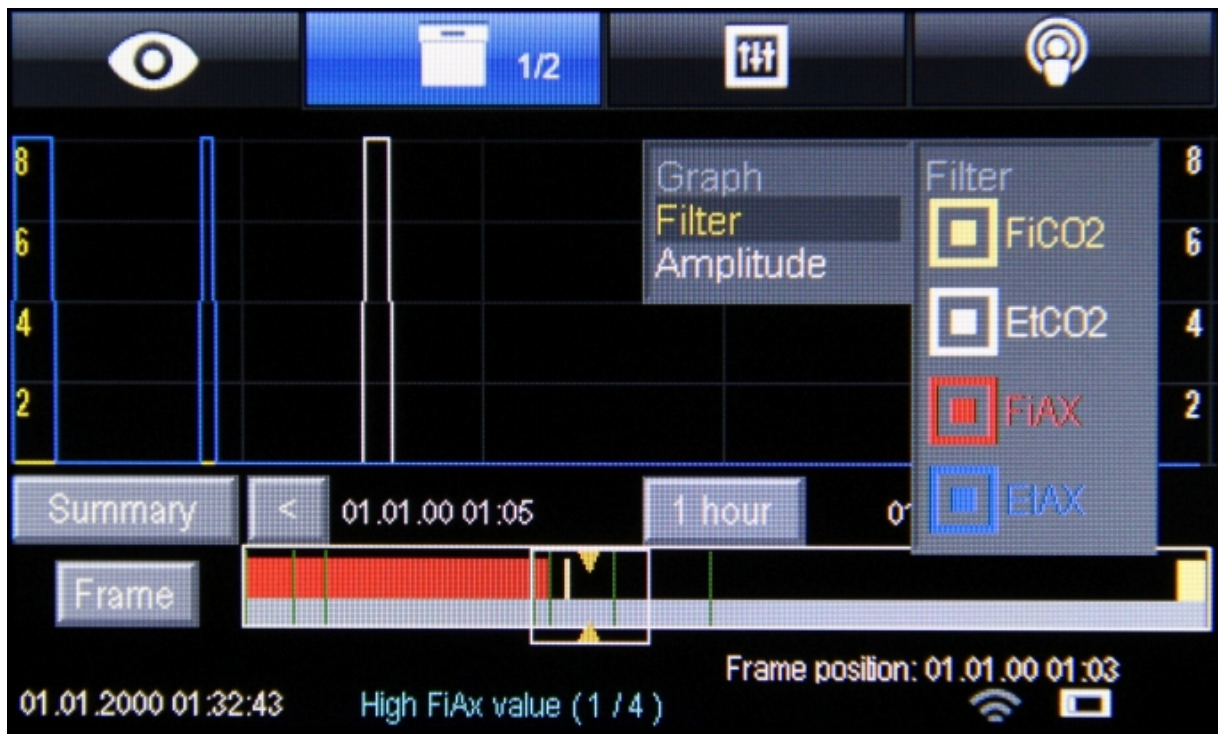
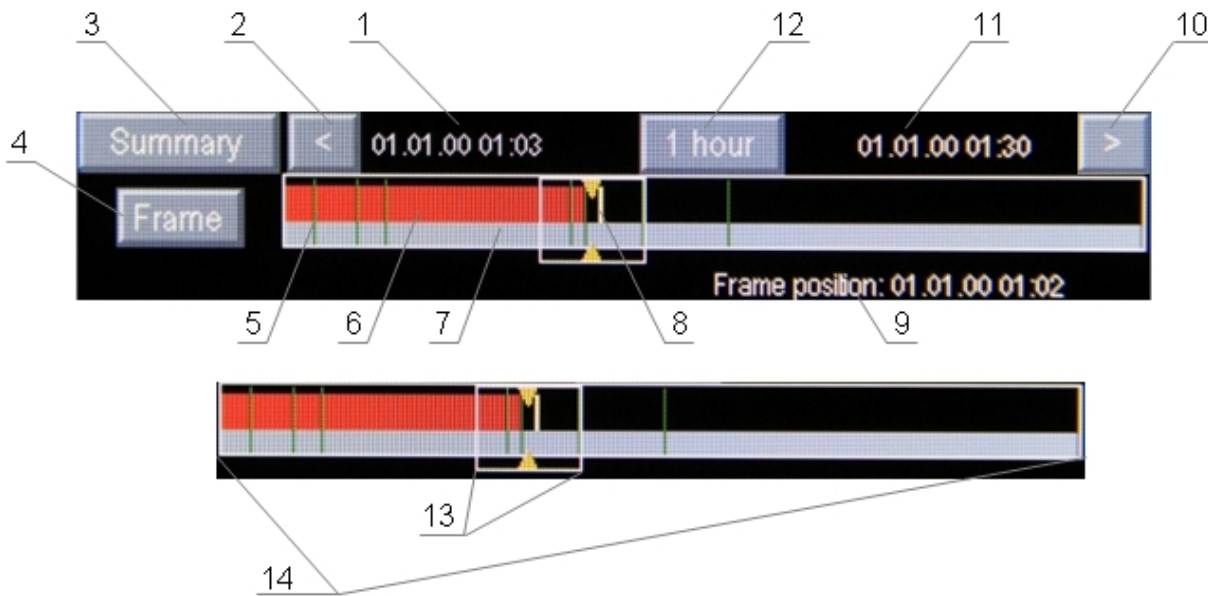


Figure 1.18 – Filter setting

Trends graph navigation occurs with a navigation panel by moving frame and scroll area. Navigation panel is situated at the bottom of the “Trends” and “Alarm log” screens. The navigation panel can be displayed in two forms:

- Navigation panel with scroll area;
- Navigation panel with frame view.

The navigation panel with scroll area shows a summary alarm graph during a set time by scroll area length button. The navigation panel with scroll area is shown in Figure 1.19. The navigation panel switches to a navigation panel with frame view by pressing the “Summary” button. In order to return from a navigation panel with frame view, it is needed to press the “Channels” button. For scrolling a scroll area during one half of length, it is needed to press the scroll left or the scroll right button in order to move scroll area back and forward, accordingly. For moving the frame, it is necessary to press the frame and move it without release. The scroll area has time start and time end markers. The frame has a frame position marker that shows current center position time of the frame.



- 1 - Scroll area start time marker;
- 2 - Scroll left button
- 3 - "Summary" button;
- 4 - Frame size button;
- 5 - Power on marker;
- 6 - High alarm marker;
- 7 - Event alarm marker;
- 8 - Medium alarm marker;
- 9 - Frame position marker (center frame time);
- 10 - Scroll right marker;
- 11 - Scroll area end time marker;
- 12 - Length scroll area button;
- 13 - Frame;
- 14 - Scroll area (summary alarm graph).

Figure 1.19 – Navigation panel with scroll area

The scroll area and frame view channels may contain the following graphical information:

- Power on markers – vertical line, 100% height, green color;
- Event markers – vertical line, 40% height, gray color;
- Low priority alarm markers – vertical line, 90% height, blue color;
- Medium priority alarm markers – vertical line, 90% height, yellow color;
- High priority alarm markers – vertical line, 90 height, red color.

Alarm markers have overlap according to the priority. The power on markers overlap other markers.

Note: the scroll area time start and end markers, frame position marker show real date and time which were set in the device when alarm happened. The “Alarm log” screen displays the real time of alarms and events occurrence. Real time does not affect the duration of alarms/events displayed in the alarm table.

For setting frame size, it is necessary to press the frame size button and select one value in percent (12,5; 25; 50; 100) as it is shown in Figure 1.20.

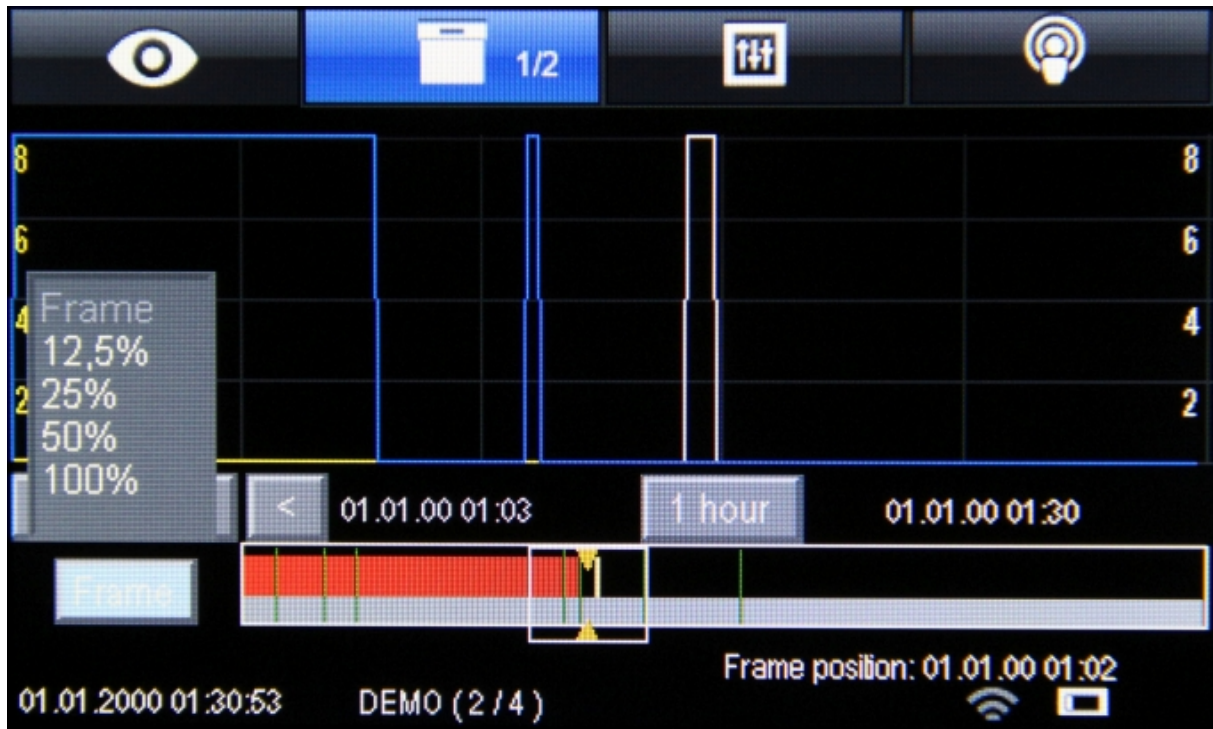


Figure 1.20 – Navigation panel, Frame setting

For setting length of the scroll area, it is necessary to press the scroll area length button and select one value in hour as it is shown in Figure 1.21.

When the length of the scroll area or frame size position is changed, the scroll area will be set to the current time. After clearing the log data or when moving the scroll area via the scroll left or scroll right buttons, there is a possibility of not displaying the data, which is in the scroll area or channels area in the navigation panel with frame view. In this case, a white middle line in the scroll area and channels area at the place without log data will be displayed.

The navigation panel with the frame view shows alarm/event channels graph during a set time by using the frame size button. The navigation panel with frame view is shown in Figure 1.22. The navigation panel with frame view has time start and time end markers of the frame. The navi-

gation panel with frame view contains two channels:

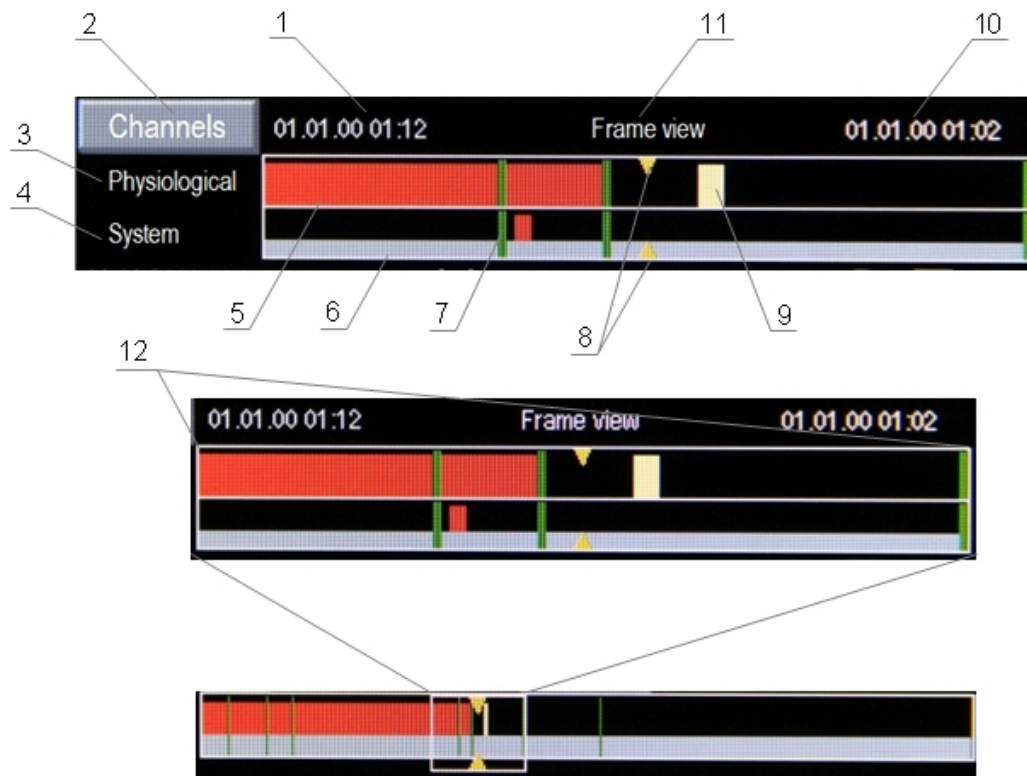
- Physical – contains only physical alarms and power on markers.
- System – contains technical alarms, events and power on markers.



Figure 1.21 – Navigation panel, Scroll area length setting

More detailed information about alarms and events is given in section 2.3 “Alarm system”.

The navigation panel with frame view contains an alarm pointer that can be moved by pressing the channels area. The influence of an alarm pointer position on the alarm table generation is displayed in the “Alarm log” screen. Positions of the scroll area, frame and alarm pointer are saved when switching between the “Trends” and “Alarm log” screens. After switching to the other screen, for example the “Monitoring” screen, the scroll area at the next switching to the “Trends” screen will be set at the current time end. An alarm pointer position does not affect the trend graph window. More detailed information about the influence of an alarm pointer on the alarm table generation is given in section 1.3.3 “Alarm log” screen. The channels area displays a frame time period and draws alarms/events which the frame contains at present.



- 1 - Frame start time marker;
- 2 - “Channels” button;
- 3 - Title of physical channel;
- 4 - Title of system channel;
- 5 - High alarm marker;
- 6 - Event alarm marker;
- 7 - Power on marker;
- 8 - Alarm pointer;
- 9 - Medium alarm marker;
- 10 - Frame end time marker;
- 11 - Title frame view;
- 12 - Channels area;

Figure 1.22 – Navigation panel with frame view

1.3.3 “Alarm log” Screen

CAUTION



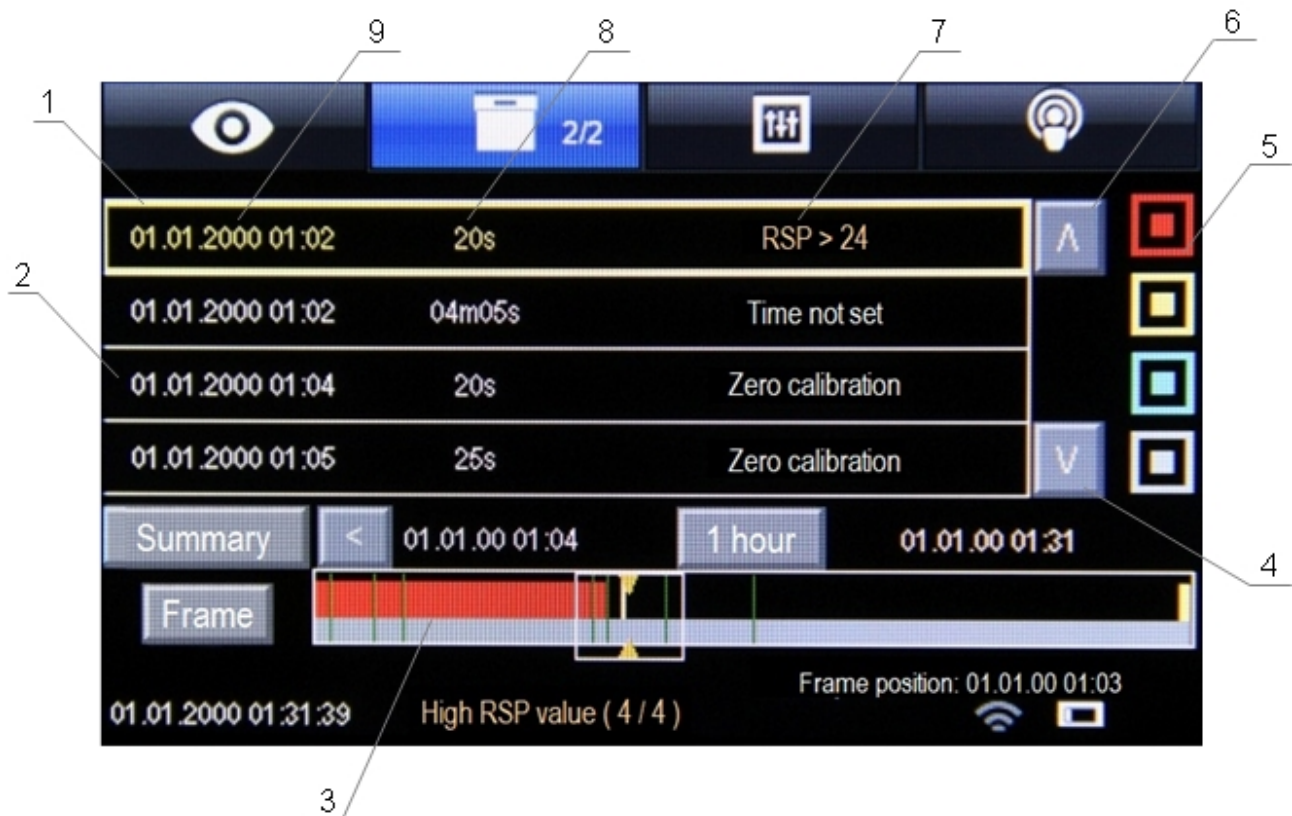
It is necessary to clear alarm and event log as well as patient information after each use and before putting into operation, maintenance, and shipment for repair to the manufacturer. Press button “Clear patient info” in the “Advance Settings” window to clear patient info (see p. 1.3.5).

The “Alarm log” screen is a continuation of the “Trends” screen. To enter the screen, press the “Trends” tab in the “Trends” screen. The screen will be displayed in accordance with Figure 1.23. Alarm log is presented in a table, which contains date, duration and description of an alarm or

event. The table filter is located on the right side of this window.

Each row of the alarm table, depending on the priority, is displayed in a certain color:

- high priority alarm - red;
- medium priority alarm - yellow;
- low priority alarm – blue;
- events – gray;
- power on events – green.



- 1 - selected row;
- 2 - alarm table;
- 3 - navigation panel;
- 4 - forward scroll button;
- 5 - alarm filter;
- 6 - back scroll button;
- 7 - description of an alarm or event;
- 8 - duration of an alarm or event;
- 9 - date when start alarm or event;

Figure 1.23 – “Alarm log” screen

The alarm log table is generated relative to the alarm pointer located in the channels area of the navigation panel (to switch to this area, press the button “Summary”, see Figure 1.23). Moving the frame also changes a position of the alarm pointer. The selected row with yellow border color and previous rows (rows above selected row) are generated from the alarm pointer at the left side

of the alarm pointer position. Subsequent rows are generated at the right side of an alarm pointer position.

Note: the alarm table is not a static list of alarms or events. A user should consider the logic of forming the alarm table and examples.

New table generation starts when the alarm pointer changes its position or it is initial alarm table generation. The alarm pointer changes its position when the selected row is changed by pressing on other row.

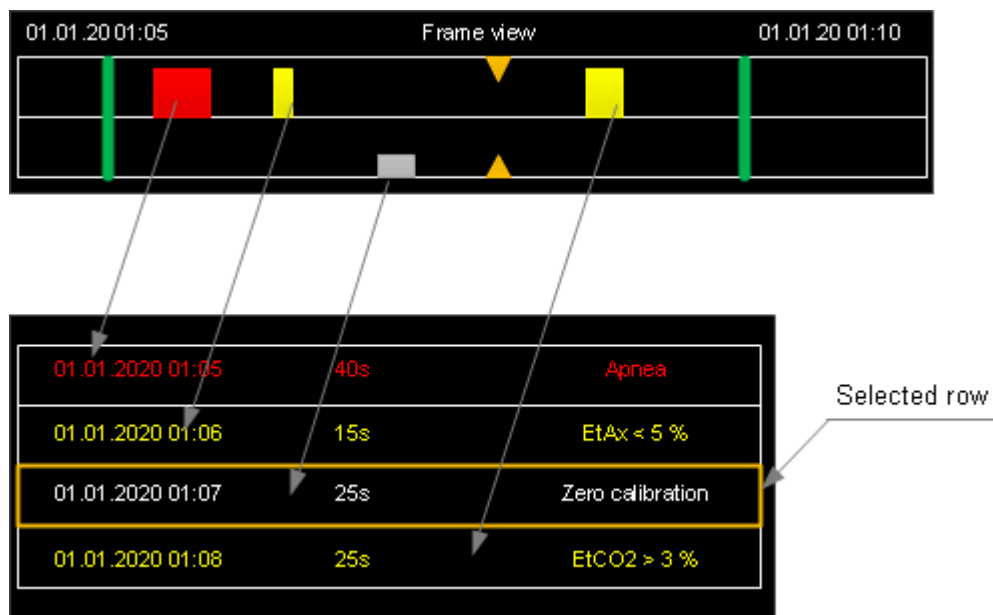


Figure 1.24 – Alarm table generation, example 1

Figure 1.24 illustrates an alarm table generation with arrows, showing alarm and event row positions for this example.

Possible is a case when start time of the row with an alarm or event will be less than start time of the previous row with an alarm or event (Figure 1.25). This case is also possible if the device’s date and time are changed during its operation.

The back and forward scroll buttons are intended for scrolling the alarm table back and forward, accordingly.

If the alarm is active and not resolved, then the active message will be displayed in the column with duration.

After the device is switched on, correction of the previously active alarms takes time. One minute later the active message will be correct.

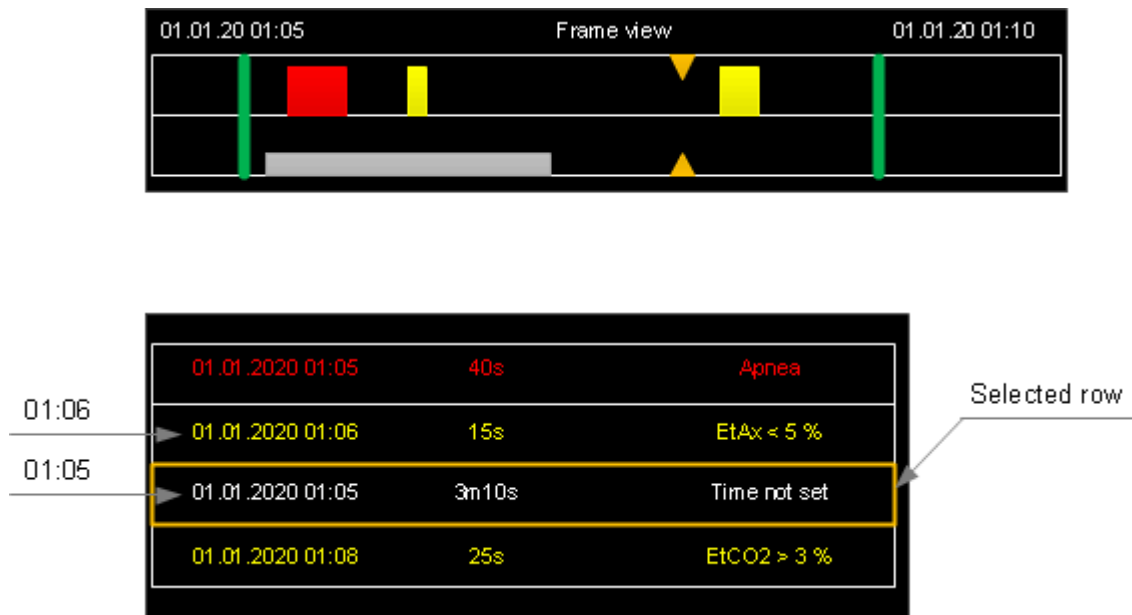



Figure 1.25 – Alarm table generation, example 2

1.3.4 “Settings 1” and “Settings 2” Screens



WARNING

For patient safety it is strongly recommended not to turn off the alarm completely. It can lead to omission of an alarm situation and harm a patient or the device.



CAUTION

Internal clock keeps functioning even if the device is switched off. However, if the device is stored in off mode for an extended period of time or if the battery is discharged, time and date can be reset to factory settings, (01/01/2000 01:01:01). In this case, turn on the device and set the time and date.

The “Settings 1” and “Settings 2” screens are intended for setting required parameters and changing the displayed data type and scale. Press the “Settings (1 and 2)” tab to enter the «Settings 1» screen. The corresponding information according to Figure 1.26 appears on the screen.

Parameters available for changing in the «Settings 1» screen are divided in two types - customizable parameters and switchable parameters.

Customizable parameters: FiCO₂ high limit, EtCO₂ high limit, EtCO₂ high limit, FiAx high limit, FiAx low limit, EtAx high limit, EtAx low limit, RSP high limit, RSP low limit, apnea.

Switchable parameters: anaesthetic, unit.

Anaesthetic parameter list: ISO (isoflurane), SEV (sevoflurane), DES (desflurane). DES pa-

parameter is available if the checkbox «Use Desflurane» in the «Settings 2» screen is checked.

Apnea detection works after 5 respiration cycles and the apnea detection time increases by 15 seconds if zero calibration occurs during apnea detection process. The apnea detection time should be longer than the respiratory cycle time. The countdown of the fixation time for apnea is performed after each change in the phase of the respiratory cycle.



- 1 - Parameter value;
- 2 - selected parameter;
- 3 - unselected parameter;
- 4 - “-” button to decrement the value
- 5 - slider;
- 6 - “+” button to increment the value.

Figure 1.26 – “Settings 1” screen

Unit parameter list: %, mmHg, kPa. FiCO₂, EtCO₂, FiAx, EtAx parameters will be recalculated when the parameter «Unit» is changed.

Press on the parameter for selection in order to change a value. The slider and the “+”/“-” buttons enable to set the necessary value.

In the «Settings 1» screen, press the “Settings (1 and 2)” tab to enter the «Settings 2» screen.

Parameters available for changing in the «Settings 2» screen are customizable parameters.

The «Settings 2» screen contains the calibration button, checkboxes and atmospheric pressure value.

Customizable parameters: sweep speed, volume, flow, coefficient MAC, time and date.

Calibration button needed for manual start zero calibration process.

Checkbox «Use Desflurane» states:

- checked – enable DES in unit list in the «Settings 2» screen;
- unchecked – disable DES in unit list in the «Settings 2» screen;



- 1 - calibration button;
- 2 - day;
- 3 - month;
- 4 - year;
- 5 - hours;
- 6 - minutes;
- 7 - checkbox «Show graph value»;
- 8 - checkbox «Show FiCO2, FiAx»;
- 9 - checkbox «Use Desflurane»;
- 10 - checkbox «Use FiAx, EtAx in %»;
- 11 - atmospheric pressure.

Figure 1.27 – “Settings 2” screen

Checkbox «Show FiCO₂, FiAx» states:

- checked – FiCO₂ and FiAx windows will be displayed in the «Monitoring» screen;
- unchecked – FiCO₂ and FiAx windows will be hidden in the «Monitoring» screen.

Checkbox «Show graph value» states:

- checked – current graph CO₂ and anaesthetic values will be displayed in the «Monitoring» screen;
- unchecked – current graph CO₂ and anaesthetic values will be hidden in the «Monitoring» screen.

Checkbox «Use FiAx, EtAx in %» when checked states that the units of the anaesthetics will always be in %.

Checkbox default state when the device is switched on:

- checkbox «Use Desflurane» - unchecked;
- checkbox «Show FiCO₂, FiAx» - unchecked;
- checkbox «Show graph value» - unchecked.

Another group of the customizable parameters is the current time and date (Figure 1.27, position 2-6). It consists of a date, month, year, hour and minute. To select a part of this group, press the **Time** window within a rectangular white line. A blue mark shall appear in one of the parameters, indicating that this part of the parameters will be edited. When pressing the **Time** field, the marker will move to the right, to the next edited part of the time parameters. Sequentially moving to date, month, year, hour and minutes, stopping on the desired parameter, edit it using the slider and the “+”/“-” buttons.



Figure 1.28 - Time field of date and time correction

Volume adjustment is made by selecting the «Volume» button. Slider and the “+”/“-” buttons enable to set a necessary value. Selecting a zero volume value turns off the audible alarm, while the alarm highlight continues to function.

1.3.5 “Advanced Settings” Screen

The “Advanced settings” screen is intended for advanced setting the device, enter patient information and view the device info. To access the corresponding information (Figure 1.29), press

the “Advanced settings” tab.

In the middle of the screen there is an information block “Information”, which contains the patient's surname, name in the patient field. The status of the device connection via Wi-Fi to an external medical information system (hereinafter - MIS) is displayed in the “MIS state” field. At the bottom of the screen, the version of the software used and serial number of the device is given.

The “MIS state” field may have the following states:

- “MIS disconnected” - no data exchange with the MIS;
- “MIS connected” - data exchange with the MIS is correct.

Press the “Patient” button to open the patient parameters window.

Press the “Normal” switch button where the operating mode of the device set earlier is displayed, to select one of the available options:

- “Normal” - operating mode;
- “Demo” - demo mode.

Note: *it is recommended to turn on the demo mode after the device is warmed up (1 minute after the device is switched on).*

Press the button displaying the interface language set earlier (for example, “ENG”) for a drop-down menu to be displayed, where you can select one of the available languages:

- Croatian (“HRV”);
- Czech (“CES”);
- Danish (“DAN”);
- English (“ENG”);
- French (“FRA”);
- Italian (“ITA”);
- German (“DEU”);
- Greek (“ELL”);
- Dutch (“NLD”);
- Norwegian (“NOR”);
- Portuguese (“POR”);
- Russian (“RUS”);
- Serbian (“SCC”);

- Slovenian (“SLV”);
- Spanish (“ESL”);
- Swedish (“SVE”).

Press the “Backlight” button, displaying the brightness percentage of the display, for the “Backlight” drop-down menu. Reducing the brightness level enables a user to extend battery life.

Select one of the available brightness options from the drop-down menu shown on the right:

- “100 %” - 100 % screen backlight;
- “75 %” - 75 % screen backlight;
- “50 %” - 50 % screen backlight.

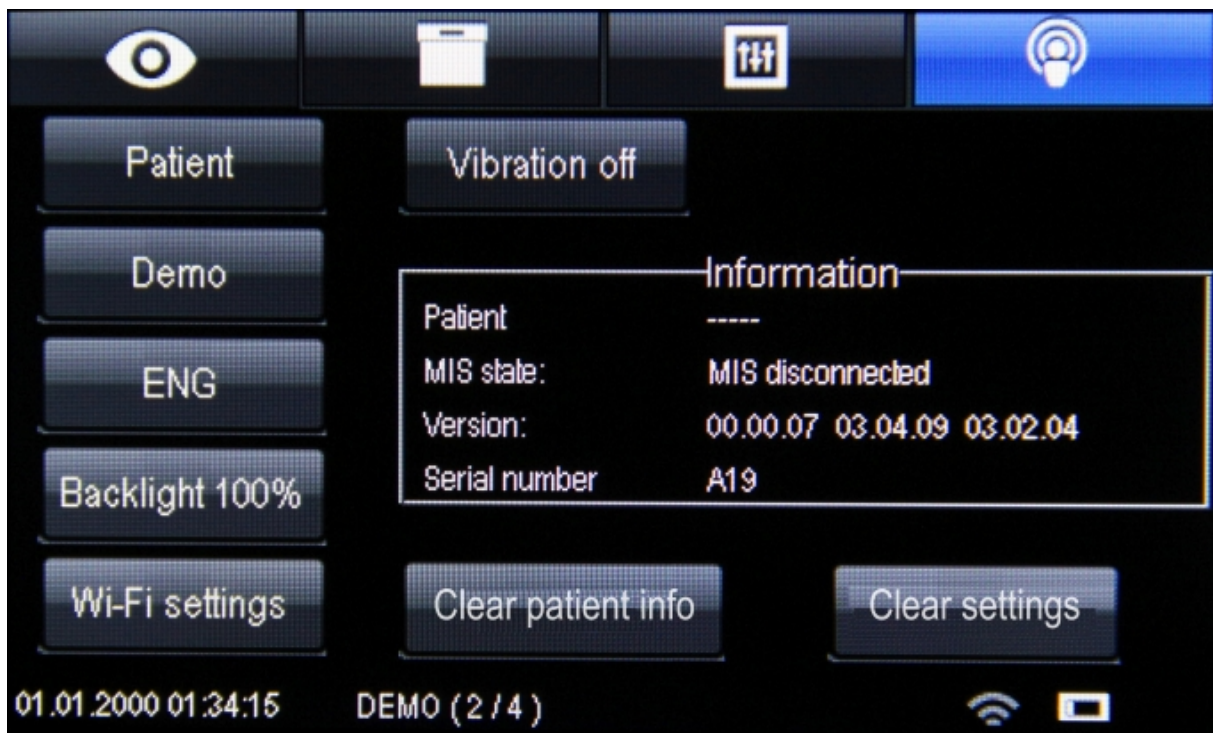


Figure 1.29 – “Advanced Settings” screen

Press the “Clear patient info” button for the pop-up menu to be displayed with two options:

- “No” - cancel clearing the patient information;
- “Yes” - clearing the patient information.

Press the “Clear settings” button for the menu to be displayed with two options:

- “No” - cancel resetting the device to factory settings;
- “Yes” - resetting the device to factory settings.

An operator cannot clear alarms (including technical alarms) and events. Only patient information can be cleared by an operator using the corresponding button.

Press the switch button “Vibration” to turn off or turn on the device vibration response to pressing the display. The button displays the current status.

Press the button “Wi-Fi settings” to bring up a window where you need to fill in the settings of the wireless network the device will be connected to.

The “Information” field contains the software version in the format: XX.XX.XX YYY.YY.YY ZZ.ZZ.ZZ, where X is the version of the indication module, Y is the version of the device measurement module, Z is the version of the battery charger microcontroller.

1.3.6 “Wi-Fi settings” Screen

Press on the “Wi-Fi settings” button in the “Advanced settings” screen to go to the window to review or modify the Wi-Fi settings. The “Wi-Fi settings” screen contains Wi-Fi parameters and virtual keyboard as shown in Figure 1.30.

Requirements for the Wi-Fi access point are given in Appendix B.

If the device is not planned to be operated as part of a network, this item does not require changes. Press the “Find net” button to display a list of currently available networks. Press on the desired wireless network to be displayed in the “SSID” line (Wi-Fi list contain max 5 items, if no desired Wi-Fi network is in the list, it is necessary to type SSID manually). To set the “SSID” manually, press on the appropriate line and use the keyboard to enter the identifier of the wireless network, and then press the “Ent” button on the virtual keyboard. More information about virtual keyboard is in the section 1.3.9 «Virtual keyboard». Then press the “Password” line and enter the password using the keyboard located at the bottom of the screen and press the “Ent” button on the virtual keyboard. Consequently, in the “AMG IP” field you will see the IP address assigned by the local network router.

To communicate with the MIS, it is necessary to press the “IP MIS” line and use the virtual keyboard to enter the IP address of the MIS in the format “xxx.xxx.xxx.xxx” and press the “Ent” button on the virtual keyboard. Press the “Start” button to connect to the Wi-Fi network. After successful connection to the Wi-Fi network, the “Wi-Fi state” field will display the “Connected” state and the “Wi-Fi” icon will turn white. After connecting the device to the medical information system and receiving confirmation from it that the parcels were received in the “MIS state” field of the “Advanced settings” screen, the status “MIS connected” is displayed and the Wi-Fi icon turns green.

In the “Wi-Fi state” field, the following states are possible:

- “init...” - Wi-Fi module is being configured after the device is turned on;
- “init error” - error in the process of setting up a Wi-Fi module after the device is turned on;
- “module ready” - successful completion of the initial setup process, Wi-Fi readiness for operation;
- “Wi-Fi search...” - Wi-Fi networks are being searched;
- “Wi-Fi not found” - there are no available Wi-Fi networks in sight;
- “Wi-Fi found” - there are available Wi-Fi networks in sight and they are displayed;
- “try connect...” - you are connecting to a Wi-Fi access point;
- “disconnection Wi-Fi” - a disconnection from a Wi-Fi access point is underway;
- “Wi-Fi disconnected” - no connection to a Wi-Fi network;
- “Wi-Fi connected” - there is a connection to a Wi-Fi network;
- “Setting IP” - setting the IP address of the device received from the access point's DNS server;
- “IP set” - the device IP address has been set;
- “IP not set” - the device IP address can not be set.



1 - Wi-Fi settings;
 2 - virtual keyboard;

Figure 1.30 - “Advanced settings” screen, Wi-Fi network operation

1.3.7 “Patient Information” Screen

To go to the screen for viewing and editing patient parameters, proceed to the “Advanced settings” screen and press the “Patient” button. Patient information contains three pages of information with named strings. All pages are shown in Figures 1.31, 1.32, 1.33. Left part of the page is the name of the necessary information about the patient, the central part of the page has to be filled by the operator of the device. The pages are switched when you press the bookmarks located on the right side of the screen (1/1, 1/2, 1/3). The name of the currently active page is highlighted in yellow, the active page 1 is in Figure 1.31.

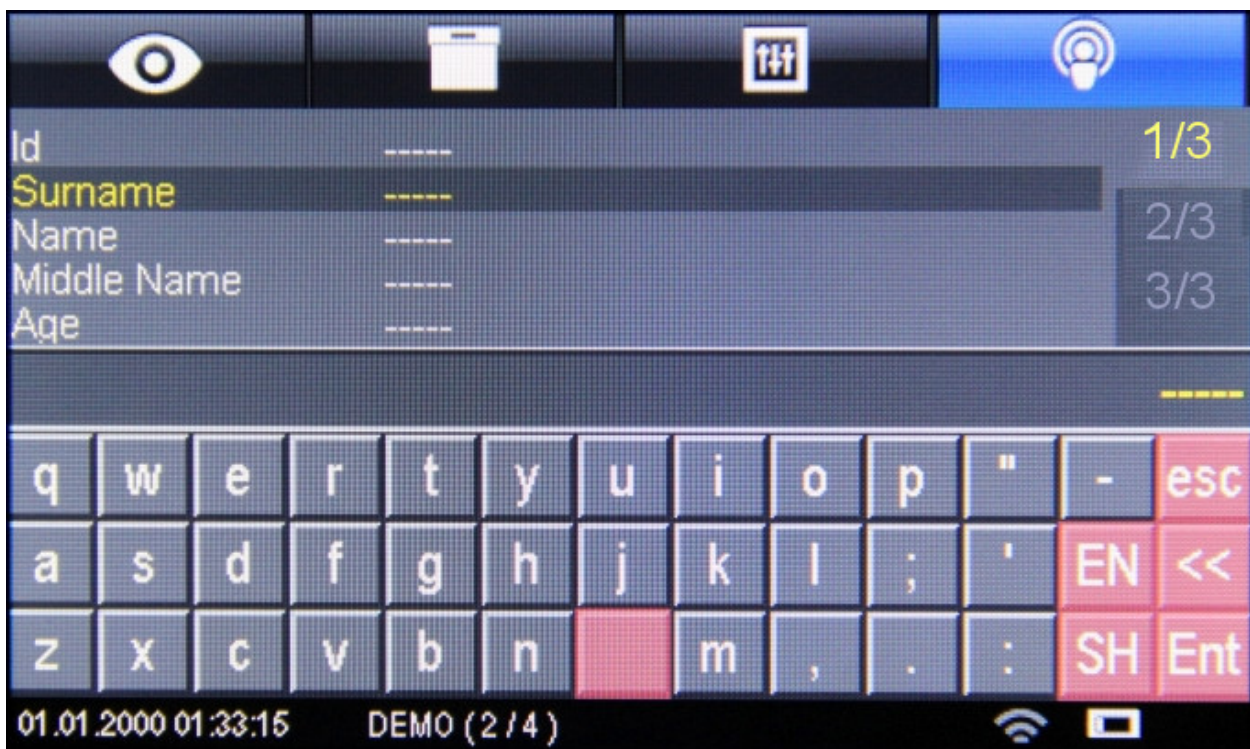


Figure 1.31 - “Patient information” window (Page 1)

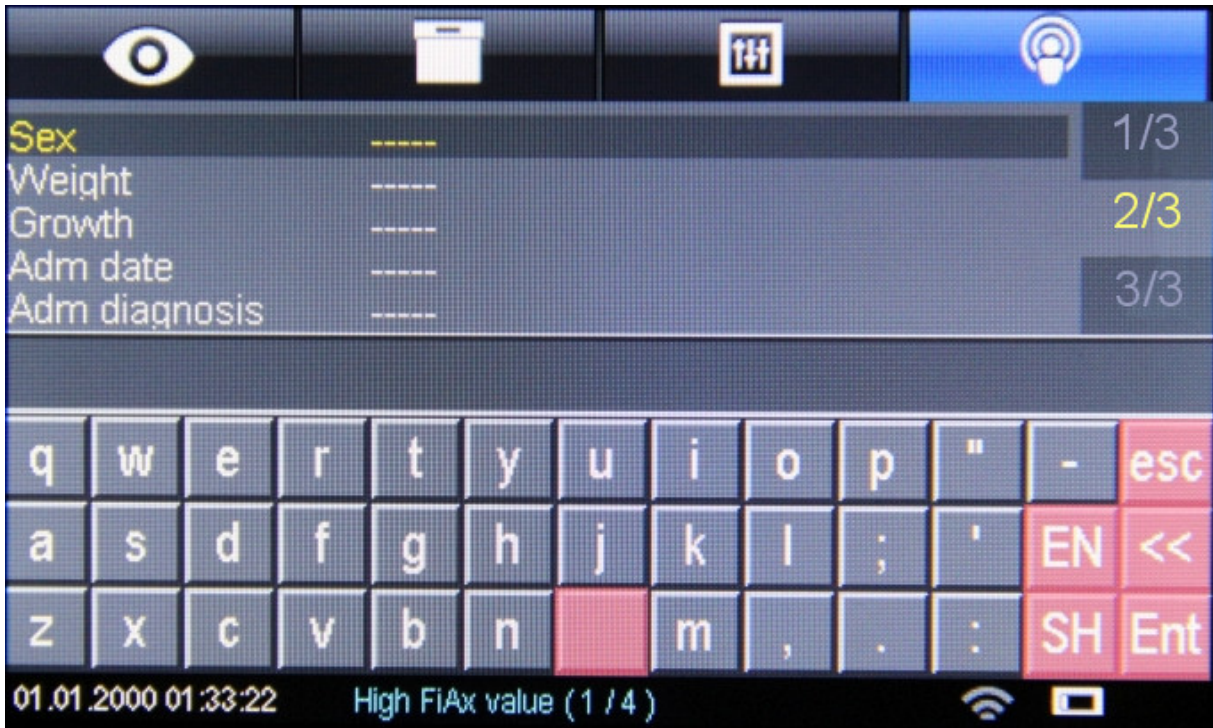


Figure 1.32 - "Patient information" window (Page 2)

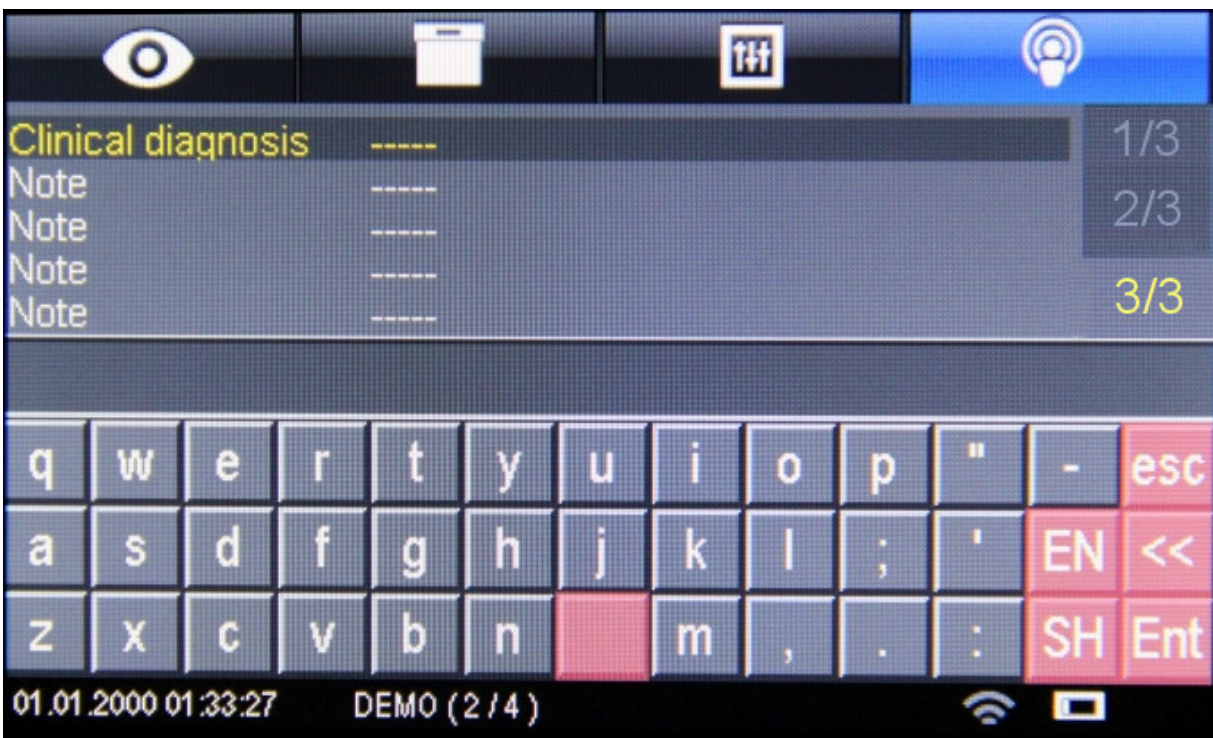
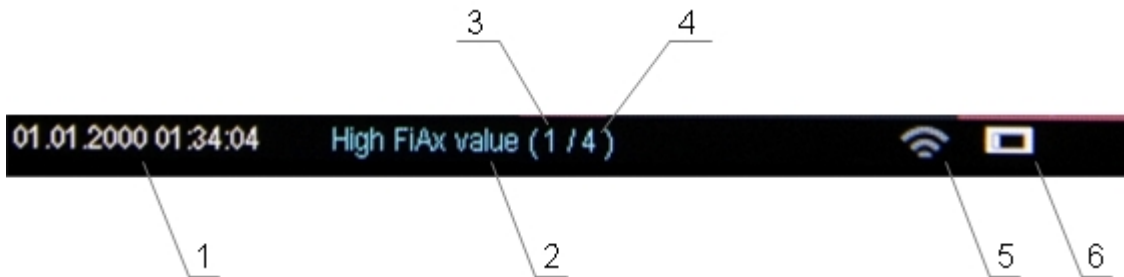


Figure 1.33 - "Patient information" window (Page 3)

Press the desired line to change the parameter and it will be highlighted in yellow. Using the virtual keyboard, a user can enter information or edit it. To make changes, press the "Ent" button on the virtual keyboard. To exit from this window to the previous menu, press the "esc" button on the virtual keyboard or go to any other window by pressing the appropriate tab.

1.3.8 Status Line

The status line is shown in Figure 1.34.



- 1 - *Date and time;*
- 2 - *the name of the alarm or event;*
- 3 - *alarm number or event in the list of active alarms and events;*
- 4 - *the number of active alarms and events;*
- 5 - *Wi-Fi pictogram/RS232 pictogram;*
- 6 - *battery charge level.*

Figure 1.34 - Status line

This element is located at the bottom of each window and displays alarms and events.

Status line contains:

- name of the event or alarm;
- event or alarm number in the list of active alarms and events;
- number of active alarms and events.

Each name of the event or alarm, depending on the priority, is displayed in a certain color:

- high priority alarm - red;
- medium priority alarm - yellow;
- low priority alarm – blue;
- events – gray;

The status line displays only currently active alarms and events. If there are several alarms and events, the active alarms and events are automatically scrolled with an interval of 2.5 sec.

RS232 pictogram is displayed instead of Wi-Fi pictogram when the device is connected by RS232 interface.

1.3.9 Virtual Keyboard

This element is located in the “Wi-Fi settings” and “Patient Information” windows.



Use the virtual keyboard to enter the information. There are two groups of keys on the keyboard: gray and red. Alphanumeric keys of the keyboard are marked in gray. The control keys and the space bar are marked in red. Control key for switching the keyboard language (hereinafter referred to as keyboard layouts) changes its inscription in accordance with the currently displayed keyboard layout, in the figure 1.30, this is the “EN” key and the keyboard with English letters is displayed. The national keyboard layout inscriptions are:

- Croatian - HR;
- Czech - CS;
- Danish - DA;
- English - EN;
- French - FR;
- Italian - IT;
- German - DE;
- Greek - EL;
- Dutch - NL;
- Norwegian - NO;
- Portuguese - PT;
- Russian - RU;
- Serbian - SR;
- Slovenian - SL;
- Spanish - ES;
- Swedish - SV.

The national keyboard layouts always have the English keyboard layout. If user presses this key again, it will change its inscription to “123” and the numbers will appear on the keyboard buttons. The next time the user presses the key to change the keyboard layout, it switches to the English keyboard again. The “SH” control key changes the current keyboard layout, enabling the user to enter text in the selected language, but with a capital letter, or in the case of a numeric keypad, enable the user to type special characters. The key to erase the entered character is “<<”. To return the previous mode press “esc”, to enter information press “Ent” key. The virtual keyboard is shown in Figure 1.30.

2 PREPARING FOR OPERATION

2.1 DISINFECTION

| | |
|---|---|
|  | <p><u>WARNING</u></p> <p>When disinfecting the power cable by pulling through a disinfecting swab, do not apply excessive tensile forces to the cable.</p> |
|  | <p>PROHIBITION</p> <p>Do not disinfect the device that is switched on.</p> |
| | <p>PROHIBITION</p> <p>Avoid the liquid ingress into the housing and display of the device during disinfection.</p> |
| | <p>PROHIBITION</p> <p>Do not reuse single-use accessories having the appropriate marking.</p> |
| | <p>PROHIBITION</p> <p>Do not apply sterilization.</p> |
| | <p>PROHIBITION</p> <p>Do not disinfect the cable by immersion in disinfectant solution.</p> |



CAUTION

Cleaning and disinfection shall be carried out after each use, before putting into operation, maintenance or sending to the manufacturer for repair.

Cleaning and disinfection of the exterior surface of the device shall be done by wiping with gauze moistened with a cleaning and disinfecting solution. Excess liquid shall be wrung out beforehand to prevent its seeping into the device.

Recommended cleaning agents are:

- ionic surfactant solution 0.5 %;
- neutral soap;
- Neodisher Mediclean forte 1 % by Dr. Weigert.

Recommended disinfection agents are:

- hydrogen peroxide solution 3 %;
- ethanol or isopropyl solution 70 %;

- chlorhexidine gluconate solution 0.5 %;
- benzalkonium chloride solution 0.2 %;
- benzethonium chloride solution 0.2 %;
- Sekusept aktiv by Henkel-Ecolab.

It is possible to use other patented products that include similar active ingredients in appropriate concentrations.

Cleaning and disinfection procedure

1. Turn off the device; disconnect the power adapter from the mains.
2. Exterior surfaces of the device shall be cleaned and disinfected as described above.
3. Gently wipe touchscreen of the device with soft cloth, dampened with a neutral detergent, then wipe dry with a soft fibreless cloth. To avoid touchscreen damaging, do not apply force during processing.
4. The device must be dried completely before connecting to the mains and usage.

2.2 POWER ON

CAUTION



Before using a new battery and after long period of storage, it might be necessary to cycle (charge, then discharge) the battery a few times to get full charge capacity. REMEMBER that operation features of the battery shall be taken into account (see p. 3.5).

CAUTION

Do not switch the device on immediately after its switching off. It takes at least 5 seconds to switch the device on again. The ON/OFF button is out-of-operation within these 5 seconds.

To prepare the device for operation, follow these steps:

For operation from the mains power supply, connect the power cable of power adapter to corresponding connector on the front panel of the device. The device is ready for use when the light of "Power" and "Bat." indicators is blue.

When the device is operated from the internal battery, no user's manipulation is required. In this case "Power" indicator is not lighted, while light of "Bat." indicator is white.

Press the ON/OFF button on the front panel of the device, and then the display will be lighted and in a few seconds be ready for operation. Light of the "Power" indicator turns white. "Bat." indicator turns off.

Press the ON/OFF button once again to switch the device off. The display turns off. (The device can be switched on again only in at least 5 s before "Meas. module warming-up" state).

To disconnect the cable from the device, carefully grasp the connector and pull.

2.3 ALARM SYSTEM



WARNING


A hazard can exist if different alarm presets are used for the same or similar equipment in any single area e.g. an intensive care unit or cardiac operating theatre.



CAUTION

If there are no active alarms, the indicators on the front panel operate as the “Power” indicator and the “Bat.” indicator.

CAUTION

Alarm sound can be paused with  button for 2 minutes (in the “Monitoring” window).

1) Terms

Event - what happens in the device in a certain point of time (e.g.: value goes beyond limits (e.g.: $\text{FiCO}_2 > 50$), fixing a dangerous sign (e.g.: low FiAx), operator's actions (switching the device on), technical message (e.g.: “Time not set”).

Alarm - a negative event usually to be signaled about.

Priority of alarm - the level of alarm danger: low, medium, high.

2) Classification

There are three types of events:

- physiological alarms - determined by a patient status (when monitored parameters exceed alarm limits);
- technical alarms – device malfunctioning;
- technical events – notifications about device status.

The term “Events” is used in this document and in the device interface instead of the “Technical events”.

Alarm limits are displayed near a numeric value of monitored parameters (Figure 1.11).

There are two forms of alarms:

- visual alarm (includes screen messages and indicator on the front panel);
- sound alarm.

The type of a signal depends on the alarm level.

Physiological alarms are displayed in the alarm log with a limit value and sign “>” or “<”, and depending on going beyond the upper or lower limits are violated by current value of the parameter (i.e. “RSP > 15”).

Table 2.3 - Types of alarm

| Priority of alarm | Visual alarm | Audible alarm |
|-------------------|---|------------------------------------|
| High priority | Information message at the bottom of the screen The indicator light flashes red. In the case of a physiological alarm, the parameter value is displayed in white on a red background The exceeded alarm limit is displayed in red on a yellow background | Ten short signals every 10.5 sec |
| Medium priority | Information message at the bottom of the screen The indicator light flashes yellow. In the case of a physiological alarm, the parameter value is displayed in white on a yellow background The exceeded alarm limit is displayed in red on a yellow background | Three short signals every 16.1 sec |
| Low priority | Information message at the bottom of the screen The indicator light is constantly yellow | One short signal every 38.0 sec |

In case of several technical alarms, the on-screen messages are displayed sequentially.

When several alarms occur simultaneously, a high priority alarm signal is generated. Messages about other alarms are displayed in the area of alarms list.

Low alarm priority is indicated in a blue color in the area of alarms and events in the “Trends” window, and by a sound signal with an interval 38.0 seconds between pulse series and effective pulse duration of 168 ms in the amount of 1 pulse.

The medium alarm priority is displayed in a yellow color in the alarm and event area in the Trends window, and on the background of the parameter widget, by flashing at a frequency of 0.8 Hz, and also by a sound signal with an interval of 16.1 seconds between pulse series and effective duration of 164 ms in the amount of 3 pulses with an interval between pulses of 220 ms.

The high alarm priority is displayed in a red color in the alarm and event area in the Trends window, and on the background of the parameter widget, by flashing at a frequency of 2 Hz, and also by a sound signal with an interval between pulse series of 10.5 sec and effective duration of 168 ms in the amount of 10 pulses with an interval between 1 and 2 pulses of 110 ms, between 2 and 3 pulses of 110 ms, between 3 and 4 pulses of 390 ms, between 4 and 5 pulses of 110 ms, between 5 and 6 pulses of 660 ms, between 6 and 7 pulses of 110 ms, between 7 and 8 pulses of 110 ms, between 8 and 9 pulses of 390 ms, between 9 and 10 pulses of 110 ms.

In the output field of alarms and events in the “Trends” window, events are indicated in gray (except the “Power on” event, which is displayed in green). Alarms and events are recorded in the

alarm log and, if necessary, are displayed in the status line, see table 2.4. The alarm log is stored in the memory, but is displayed graphically in the “Trends” window.

The status line and alarm events differ in priorities: red – high priority, yellow - medium priority, blue color - low priority. An information message about a technical event in the status line is displayed in gray or green only for the power on event.

The status line is implemented with an automatic scrolling of alarms and events with a frequency of 0.4 Hz. In the status line, if several alarms occur at the same time, the number and order of events are displayed, e.g.: “Time not set (2/5)”.

The alarm response time for any of the monitored parameters is maximum 20 s.

If the alarm system has experienced a total loss of power (supply mains and/or internal electrical power source) for a finite duration, contents of the log will be stored in non-volatile memory of the device.

Alarms are recorded in the log repeatedly. All the alarms (according to table 2.4) are recorded during 72 hours, every 5 s. The log is stored in non-volatile memory of the device.

The noise level generated during normal operation of the device should be maximum 50 dB.

The maximum adjustable volume level of alarm signals must be at least 40 dB.

The volume level of alarm signals should be maximum 80 dB.

Alarm limits in manufacturer-configured alarm presets:

- RSP low limit - 5,
- RSP high limit - 40,
- FiAX, EtAX low limit - 0%,
- FiAX, EtAX high limit - 4%,
- EtCO2 low limit - 3.5%,
- EtCO2 high limit - 7.5%,
- FiCO2 high limit - 1%,
- MAC high limit is fixed and equal to 3.00, MAC coefficient is 1.00,
- Apnea time 20 sec.

These limits are default until the first change is made by a user, then settings will be stored in the memory.

During adjustment of any alarm limit or operator-adjustable alarm preset, the alarm system shall continue operating normally.

Table 2.4 – Alarms and events

| No | Alarm message | Priority | Alarm conditions | Indication, operator’s actions |
|----------------------|---------------|----------|------------------|--------------------------------|
| physiological alarms | | | | |

| No | Alarm message | Priority | Alarm conditions | Indication, operator's actions |
|----|------------------------------|----------|--|--|
| 1 | Apnea | High | No breath | Message in the status line and alarm log, background RSP flashing red Check the patient. |
| 2 | Low RSP value | Medium | Low respiratory rate value | Message in the alarm log, background RSP flashing yellow Check the patient. |
| 3 | High RSP value | Medium | High respiratory rate value | Message in the alarm log, background RSP flashing yellow Check the patient. |
| 4 | High FiCO ₂ value | Medium | High carbon dioxide concentration at inspiration | Message in the alarm log, background FiCO ₂ flashing yellow Check the patient and anesthesia device. |
| 5 | High EtCO ₂ value | Medium | High carbon dioxide concentration at expiration | Message in the alarm log, background EtCO ₂ flashing yellow Check the patient. |
| 6 | Low EtCO ₂ value | Medium | Low carbon dioxide concentration at expiration | Message in the alarm log, background EtCO ₂ flashing yellow Check the patient. |
| 7 | High FiA _x value | Medium | High anaesthetic concentration at inspiration | Message in the alarm log, background FiA _x flashing yellow Check the patient and anesthesia device. |
| 8 | Low FiA _x value | Medium | Low anaesthetic concentration at inspiration | Message in the alarm log, background FiA _x flashing yellow Check the patient and anesthesia device. |
| 9 | High EtA _x value | Medium | High anaesthetic concentration at expiration | Message in the alarm log, background EtA _x flashing yellow Check the patient and anesthesia device. |

| No | Alarm message | Priority | Alarm conditions | Indication, operator's actions |
|------------------|------------------------|----------|---|---|
| 10 | Low EtAx value | Medium | Low anaesthetic concentration at expiration | Message in the alarm log, background EtAx flashing yellow Check the patient and anesthesia device. |
| 11 | MAC > 3 | Medium | High MAC value | Message in the alarm log, background MAC flashing yellow Check the patient, anesthesia device, or entered MAC coefficient. |
| technical alarms | | | | |
| 1 | Inlet port occlusion | High | Inlet port occlusion | Message in the status line and alarm log Check the sampling tube and water trap for clogging, replace if necessary. |
| 2 | Outlet port occlusion | High | Outlet port occlusion | Message in the status line and alarm log Check the exhaust gas tube for clogging, replace if necessary. |
| 3 | Power system error | Medium | Power system error | Message in the status line and alarm log |
| 4 | Battery low charge | Low | Battery low charge | Message in the status line and alarm log Connect the device to the mains power to charge the battery. |
| 5 | Wrong anaesthetic type | Low | Selected wrong anaesthetic type | Message in the status line and alarm log Select the appropriate anaesthetic. |
| 6 | Meas. module off | High | Measurement module off | Message in the status line and alarm log Restart the device by ON/OFF button. Contact service department. |
| 7 | Meas. module error | High | Measurement module error | Message in the status line and alarm log Restart the device by ON/OFF button. Contact service department. |

| No | Alarm message | Priority | Alarm conditions | Indication, operator's actions |
|------------------|--------------------------|----------|--|---|
| 8 | Water trap disconnected | High | Water trap is disconnected | Message in the status line and alarm log |
| 9 | Wi-Fi error | Low | Wi-Fi module error | Message in the status line and alarm log |
| technical events | | | | |
| 1 | DEMO | --- | DEMO mode on | Icon and Message in the status line and alarm log |
| 2 | Flow: value | --- | Set flow rate | Message in alarm log |
| 3 | Apnea sec: value | --- | Set new apnea detection time | Message in alarm log |
| 4 | Clear alarm | --- | Button "clear alarm" is pressed (reset apnea or occlusion alarm) | Message in alarm log |
| 5 | Power on | --- | Power on | Message in alarm log |
| 6 | Mains power connected | --- | Mains power connected | Message in the status line and alarm log |
| 7 | Mains power disconnected | --- | Mains power disconnected | Message in the status line and alarm log |
| 8 | Volume: value | --- | Sound volume changed | Message in alarm log |
| 9 | Date changed | --- | Date changed | Message in alarm log |
| 10 | Time not set | --- | Time not set | Message in the status line and alarm log |
| 11 | Wi-Fi connected | --- | Wi-Fi connected | Icon and Message in the status line and alarm log |
| 12 | Wi-Fi disconnected | --- | Wi-Fi disconnected | Icon and Message in the status line and alarm log |
| 13 | RS232 connected | --- | RS232 connected | Icon and Message in the status line and alarm log |

| No | Alarm message | Priority | Alarm conditions | Indication, operator's actions |
|----|-------------------------|----------|--|---|
| 14 | RS232 disconnected | --- | RS232 disconnected | Icon and Message in the status line and alarm log |
| 15 | Sound pause | --- | Sound pause button is pressed (pause for 2 min is max) | Icon and Message in alarm log |
| 16 | Patient edit | --- | Patient info edited | Message in the alarm log |
| 17 | RSP low limit change | --- | Low RSP limit changed | Message in the alarm log |
| 18 | RSP high limit change | --- | High RSP limit changed | Message in the alarm log |
| 19 | FiCO2 high limit change | --- | High FiCO2 limit changed | Message in the alarm log |
| 20 | EtCO2 high limit change | --- | High EtCO2 limit changed | Message in the alarm log |
| 21 | EtCO2 low limit change | --- | Low EtCO2 limit changed | Message in the alarm log |
| 22 | FiAx high limit change | --- | High FiAx limit changed | Message in the alarm log |
| 23 | FiAx low limit change | --- | Low FiAx limit changed | Message in the alarm log |
| 24 | EtAx high limit change | --- | High EtAx limit changed | Message in the alarm log |
| 25 | EtAx low limit change | --- | Low EtAx limit changed | Message in the alarm log |
| 26 | Clear patient info | --- | Clear patient information | Message in the alarm log |
| 27 | MIS connected | --- | Correct transmission and reception of data from MIS | Icon and message in the alarm log |
| 28 | MIS disconnected | --- | No transmission and reception of data from MIS | Icon and message in the alarm log |

| No | Alarm message | Priority | Alarm conditions | Indication, operator's actions |
|----|-------------------------|----------|--|--|
| 29 | Zero calibration | --- | Zero calibration of measurement module | Message in the status line and alarm log |
| 30 | Meas. module warming-up | --- | Measurement module warming-up | Message in the status line and alarm log |
| 31 | Neonatal water trap | --- | Neonatal water trap is connected | Message and icon in the alarm log |
| 32 | Clear settings | --- | Reset settings to factory | Message in the alarm log |

An alarm and event is logged every 5 seconds and written to the alarm log every 1 minute. The navigation panel provides navigation accuracy of 1 minute.

Alarm checking procedure

To check the alarm system before the device operation, follow these steps:

- Turn on the device (see p. 2.2);
- Activate the Demo mode (see p. 1.3.5);
- Set the upper (or lower) limit of the monitored parameter lower (or higher) than a displayed value.
- Check the activation of the alarm system (sound and visual signals);
- Deactivate the Demo mode, by setting operating mode (see p. 1.3.5) before the operation;

List of alarms and events that are displayed in the status line are shown in table 2.5. Events without duration are displayed in the status line for 5 seconds.

Table 2.5 - List of text messages in the status line

| No | Alarms/Events | Message in the status line |
|----|------------------------------|------------------------------|
| 1 | No breath | Apnea |
| 2 | Low RSP value | Low RSP value |
| 3 | High RSP value | High RSP value |
| 4 | High FiCO ₂ value | High FiCO ₂ value |
| 5 | High EtCO ₂ value | High EtCO ₂ value |
| 6 | Low EtCO ₂ value | Low EtCO ₂ value |

| | | |
|----|---------------------------------|--------------------------|
| 7 | High FiAx value | High FiAx value |
| 8 | Low FiAx value | Low FiAx value |
| 9 | High EtAx value | High EtAx value |
| 10 | Low EtAx value | Low EtAx value |
| 11 | High MAC value | MAC > 3 |
| 12 | Inlet port occlusion | Inlet port occlusion |
| 13 | Outlet port occlusion | Outlet port occlusion |
| 14 | Power system error | Power system error |
| 15 | Low battery charge | Low battery charge |
| 16 | Selected wrong anaesthetic type | Wrong anaesthetic type |
| 17 | Measurement module off | Meas. module off |
| 18 | Measurement module error | Meas. module error |
| 19 | Water trap disconnected | Water trap disconnected |
| 20 | Wi-Fi module error | Wi-Fi error |
| 21 | DEMO mode on | DEMO |
| 22 | Mains power connected | Mains power connected |
| 23 | Mains power disconnected | Mains power disconnected |
| 24 | Time not set | Time not set |
| 25 | Wi-Fi connected | Wi-Fi connected |
| 26 | Wi-Fi disconnected | Wi-Fi disconnected |
| 27 | RS232 connected | RS232 connected |
| 28 | RS232 disconnected | RS232 disconnected |
| 29 | Device connected to MIS | MIS connected |
| 30 | MIS disconnected | MIS disconnected |
| 31 | Sound pause for 2 min | Sound pause |
| 32 | Zero calibration | Zero calibration |
| 33 | Meas. module warming-up | Meas. module warming-up |

3 OPERATION

3.1 CONNECTION OF THE DEVICE



CAUTION

When working with a ventilator, patient monitor or anaesthetic workstation, follow its user manual.

CAUTION

The gas monitor port with connected sampling tube shall be directed upward relative to the ground. This will reduce or completely prevent the patient's secretions and moisture accumulation in the gas monitor port.

CAUTION

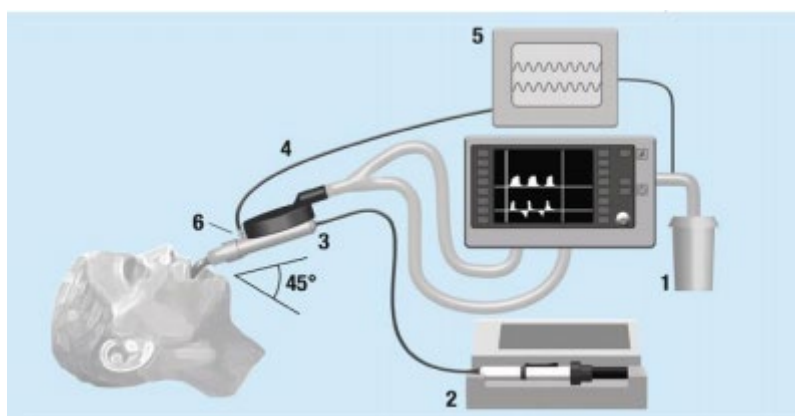
It is recommended to connect the sampling tube directly or as close as possible to the endotracheal tube to reduce dead space.

CAUTION

The device is not intended to permit the return of the sampled gas to the breathing system.

- Check the sampling tube. It must be dry and clean.
- Connect the water trap to the device slot.
- Connect the sampling tube to the gas monitor port or adapter with Luer Lock connector (T-piece or Y-piece) by turning clockwise.
- Connect the sampling tube to the inlet port of the water trap by turning clockwise.
- Connect the exhaust gas tube to gas scavenging filter and the outlet port of the device;
- Turn on the device;
- The warm-up time is about 1 minute;
- The device is ready for operation;
- After operation, disconnect the sampling tube and exhaust gas tube from the device in reverse order.

Connection of the device is shown in Figure 1.35.



- 1 - Gas scavenging filter;
- 2 - Syringe pump;
- 3 - Agent supply tube;
- 4 - Sampling tube;
- 5 - the device;
- 6 - Gas monitor port;

Figure 1.35 – Connection of the device

Check that the CO₂ desflurane, sevoflurane, isoflurane data is measured correctly in the device.

Especially when an uncuffed tracheal tube is used, the CO₂ DES, ISO, SEV partial pressure curve may be inaccurate due to leak around the tracheal tube.

Full accuracy starts after 10 minutes after the device is switched on. The ISO accuracy symbol «<*>» disappears in 10 minutes.

3.2 THE DEVICE OPERATION

During operation, the device displays the measured EtCO₂, EtDES, EtISO, EtSEV, FiCO₂, FiDES, FiISO, FiSEV, respiration rate values, CO₂ and anaesthetic curves.

The CO₂, desflurane, isoflurane, sevoflurane concentration value can be displayed on the screen as partial pressure (mmHg) and (or) as the percentage concentration (%) or kPa depending on the settings of monitored parameter and graphics.

In case of situations that prevent normal operation, the device displays the failure message.

3.2.1 Test Methods

Testing of the respiratory rate range is performed using a gas mixture with a concentration of CO₂ = 5% and air alternately fed to the device with flow rate of 250 ml/min. The measurement time for each respiratory rate should be at least 30 seconds.

To test the maximum respiratory rate depending on the flow rate, it is necessary to perform the test of the permissible absolute deviation of CO₂ concentration, consistently setting the flow rate in the device and accordingly adjusting respiratory rate in the breath imitation device.

3.3 ZERO CALIBRATION OF THE DEVICE

The device has the automatic zero calibration function. After turning the device on, during the first 10 minutes, it is calibrated every 90 seconds. After this time, zero calibration occurs if the device detects a need for it. Checking the need occurs in the first half hour every 5 minutes, and then every 15 minutes.

Manual zero calibration shall be performed when conditions change dramatically between automatic zero calibrations (pressure, temperature, etc.), and a user does not see the correct concentration measurement.

During calibration, the device displays the values before calibration, then these values are corrected when calibration stops. The calibration process takes maximum 15 min.

When apnea is detected, calibration is not activated until this alarm is cleared by a user.

3.4 MAC

Minimum alveolar concentration or MAC is the concentration of an anaesthetic in the alveoli of the lungs that is needed to prevent movement (motor response) in 50% of subjects in response to surgical (pain) stimulus.

1MAC index for anaesthetics:

- Desflurane – 6.0 %;
- Isoflurane – 1.15%;
- Sevoflurane – 2.1 %.

The data about 1MAC index refer to healthy men aged 40 years old, taken from EN ISO 80601-2-55 and correspond to the values published by the USA Food and Drug Administration and medications¹.

In actual use, there should be considered the effect of age, weight and other factors on inhalation anaesthetic.

The device uses the following expression:

$$\text{MAC} = \text{EtAX}/\text{MAC_coeff}, \quad (3.1)$$

where MAC_coeff is the coefficient that considers 1MAC and other factors.

¹ US Food and Drug Administration, Excerpts Related to EMI from Anesthesiology and Respiratory Devices Branch, November 19938, see Section (i)(7) on page 17

MAC_coeff is set in the "Settings 2" screen.

The MAC coefficient is set by a user. The calculation of the MAC is made as simple and clear as possible. The AMG-06 device does not automatically make any changes to the MAC coefficient set by a user. The MAC is calculated according to the expression. It should be taken into account, that when a user changes a type of anaesthetic in the "Settings 1" screen, the MAC coefficient will be set to the 1MAC value for the selected type of anaesthetic.

Let's consider the examples for calculating and setting the MAC:

1) $MAC = EtAX / MAC_coeff$, a user set MAC_coeff to 1.5. The current measured value of Et-Ax (expired anaesthetic concentration) is 3%. Let's substitute the values in the expression: $MAC = 3 / 1.5 = 2$. In this case, the MAC index will be equal to the value 2.

2) A user applied the anesthetic isoflurane. A user then changed the type of anesthetic to sevoflurane. In this case, the AMG-06 device will set the MAC coefficient to 2.1 in the "Coefficient MAC" field in the "Settings 2" screen. A user can then change the MAC coefficient in the "Settings 2" screen. The set MAC coefficient will be saved until the next change in the type of anesthetic.

3) The equation for calculation MAC depending on age, as well as the corresponding table for the three types of anesthetic are presented in Appendix D of this manual.

3.5 INTERNAL BATTERY



CAUTION

REMEMBER that operation features of the battery shall be taken into account.

CAUTION

Battery or charger failure does not affect operation of the device on power mains, so the device can be used in this case. But user shall take into account that back-up battery operation (at power failure) is impossible.

CAUTION

The "Battery low charge" alarm message appears in a few minutes before battery depletion. The device is switched OFF automatically, if not connected to mains power.

CAUTION

The continuous glow of the "Power" indicator in red indicates a malfunction of the power supply system of the device. This does not interfere with the work from the mains power, but if the mains power supply is lost, the device will turn off. Contact service.

CAUTION

The continuous glow of the “Bat.” indicator in red indicates a malfunction of the battery or charger. Contact service.

CAUTION

The battery shall always be charged to be ready for back-up battery operation. Ensure the battery charging after back-up battery operation.

The device has a backup power source (internal battery with charger), which provides uninterrupted self-contained operation when power cannot be supplied via the power adapter.

Capacity of the battery is decreasing during continuous service and when appropriate instructions are not followed. As a result, time of self-contained operation (running on battery) can be reduced; that is not the reason for claims to the manufacturer.

It may be necessary to cycle (charge, then discharge) the battery a few times (at least once a half a year) to get full charge capacity and to prolong its service life.

The device automatically switches to the operation from battery when mains power supply fails, and when it appears, the device also automatically resumes operation from the mains power supply. In all cases, such power transitions do not affect the operation of the device, which provides continuous monitoring.

When the device is operating from a battery, the charge level in percent is not displayed; the battery status symbol approximately reflects the charge level. When the battery status symbol is displayed in red, it indicates the battery is discharged to a critical level at which the device can turn off.

Time of back-up battery operation depends on the battery capacity, previous state of charge and time of charge, battery quality, and battery service life. Due to self-discharge effect, the battery power is reduced at storage, so actual operating time of the battery can be shorter than expected one.

A fully charged new battery will provide approximately 2 hours of operation. However, the time can be reduced without regular cycling or after long storage without recharge.

After long storage or after battery replacement, it is necessary to cycle the battery (p. 3.5.1) to ensure correct indication of charge level.

Possible states of the “Power” and “Bat.” indicators are given in tables 3.2, 3.3.

Table 3.2 – State of “Power” indicator

| Indicator Light | Device State | Mains power state | Problem |
|-----------------|--------------|-------------------|---------|
|-----------------|--------------|-------------------|---------|

| | | | |
|-------|--------------------|----------------|---|
| Off | Switched ON or OFF | NO power | - |
| Blue | Switched OFF | External power | - |
| White | Switched ON | External power | - |
| Red | Switched ON or OFF | External power | Accumulator battery failure (see section 5) |

Table 3.3 – State of “Bat.” indicator

| Indicator Light | Device State | Battery state | Problem |
|-----------------|--|--|---|
| Off | Switched OFF | Battery fully charged | - |
| Off | Switched ON Operating from external power | Battery is not charging/ Battery is charging* | - |
| Blue | Switched OFF | Battery is charging | - |
| White | Switched ON Operating from battery | Battery is not charging | - |
| Red | Switched OFF | Battery is not charging | Accumulator battery failure (see section 5) |

* level of battery charge is displayed on the screen.

3.5.1 Battery Cycling



CAUTION

It is recommended to cycle the battery regularly to support its capacity.

CAUTION

It is necessary to cycle the battery before putting the device into operation for the first time, after long storage or battery replacement. Otherwise, time of back-up operation can be reduced significantly.

To cycle the battery means to charge the battery to fully charged condition, then discharge the battery to fully discharged condition. It can be necessary to cycle (charge, then discharge) the battery a few times to get full charge capacity.

To get the battery fully discharged, disconnect the device from power mains. Then switch the device on and let it operate until the battery is fully discharged and the device automatically turns off, then the battery must be *immediately charged*.

To get the battery fully charged, connect the device to power mains; the device may not be switched on. Leave the device until the battery is fully charged.

If the device is OFF, the “Bat.” indicator shall be lighted in blue color.

If the device is ON, a displayed level of the battery charge shall be 100 %.

4 MAINTENANCE



PROHIBITION

Do not allow disinfectant liquids enter the device. Do not use the device and contact service if liquids have entered the device.



CAUTION

Before maintenance, ensure the device and its accessories to be properly disinfected.

Regular maintenance shall be performed by a device owner. This is not the responsibility of distributor or manufacturer.

Maintenance does not involve assembly/disassembly of the device and does not require special skills or knowledge. If discovered problem requires disassembly, device must be passed to the service organization authorized by Triton Electronics Systems Ltd.

| Maintenance | Frequency | Procedure and technical requirements |
|------------------------|--|---|
| Battery cycling | At least once a half a year and after long storage | Cycling procedure is given in p. 3.5.1. |

5 TROUBLESHOOTING



WARNING

Before repair, ensure the device is completely disconnected from the power mains. This may cause harm to the personnel or device.



CAUTION

Repair and service shall be performed by the organizations authorized by the manufacturer. Otherwise the manufacturer is not responsible for repair consequences.

CAUTION

During troubleshooting, follow the instructions of corresponding sections of the manual.

Please do not hesitate to contact Triton Electronic Systems Ltd by phone: +7(343) 304-60-57 or your local distributor.

| Fault condition | Probable cause | Troubleshooting |
|--|---|---|
| "Power" indicator is off when the device is connected to power mains | <ol style="list-style-type: none"> 1. No mains voltage. 2. Power adapter failure. | <ol style="list-style-type: none"> 1. Check power mains. 2. Replace power adapter. |
| Light of "Bat." indicator is red (continuous glow) | Battery/charger failure. | Contact your service technician. |
| Light of "Power" indicator is red (continuous glow) | Power supply failure. | Contact your service technician. |
| Time of operation from the battery is not sufficient | <ol style="list-style-type: none"> 1. Battery is not fully charged. 2. Decrease of battery capacity. | <ol style="list-style-type: none"> 1. Fully charge the battery. 2. Perform cycling of the battery according p. 3.5.1; if it doesn't help, replace the battery. |
| System time was reset | Result of long storage without switching ON | Charge the battery, power on the device, set current date and time |
| Audible alarm is off | Volume is set to zero level | Set the volume to desired level |
| Measurement is not performed | Bad electromagnetic environment | Turn off the devices which produce strong electromagnetic interference |
| The measured value is inaccurate | <ol style="list-style-type: none"> 1. Rapid temperature change 2. Water is accumulated in the water trap 3. Invalid zero calibration | <ol style="list-style-type: none"> 1. Measurement may be incorrect when there is a rapid temperature change 2. Remove the water from the water trap. 3. Check zero calibration of the device |

| Fault condition | Probable cause | Troubleshooting |
|---|---------------------------------|---|
| AMG module off, AMG module error | 1. AMG measurement module error | 1. Restart the device by ON/OFF button. |

6 DELIVERY SET

Delivery set is shown in Table 6.1.

Table 6.1 – Delivery set

| Name | | Part number/ Manufacturer/ Indication | Quantity, pcs. |
|------|---------------------------------------|--|----------------|
| | Multigas Analyzer AMG-06 | TESM.943129.002 | 1 |
| | Including: | | |
| 1 | Electronic unit | TESM.636000 | 1 |
| 2 | Power adapter | Cincon Electronics Co., Ltd. TR18RDM120-33G710-BK-BK VI, =12V, 1.5A, China | 1 |
| 3 | “Adult” version of water trap | DRYLINE II Water Trap ,Adult, 100-000080-00, Shenzhen Min- dray Bio-Medical Electronics Co., Ltd | 1 |
| 4 | “Neonate” version of water trap | DRYLINE II Water Trap ,Neonate, 100-000081-00, Shenzhen Min- dray Bio-Medical Electronics Co., Ltd | 1* |
| 5 | “Adult” version of sampling tube | DRYLINE Gas sampling line , Adult, 2.5m, 60-15200-00, Shen- zhen Mindray Bio-Medical Elec- tronics Co., Ltd | 1 |
| 6 | “Neonate” version of sampling tube | DRYLINE Gas sampling line , Ne- onate, 2.5m, 60-15300-00, Shen- zhen Mindray Bio-Medical Elec- tronics Co., Ltd | 1* |
| 7 | Exhaust gas tube | Oxygen tube, 1174003, 2.1m, or 1174000, 1.8m, Intersurgical, United Kingdom | 1** |
| 8 | User manual*** | TESM.943129.002UM English TESM.943129.002-01UM French TESM.943129.002-02UM German TESM.943129.002-03UM Spanish TESM.943129.002-04UM Portuguese TESM.943129.002-05UM Italian TESM.943129.002-06UM Croatian TESM.943129.002-07UM Czech TESM.943129.002-08UM Danish TESM.943129.002-09UM Greek TESM.943129.002-10UM Dutch TESM.943129.002-11UM Norwegian TESM.943129.002-12UM Serbian TESM.943129.002-13UM Slovenian TESM.943129.002-14UM Swedish | 1 |

| | | | |
|---|-----------------------|-------------|---|
| 9 | Package of the device | TESM.633000 | 1 |
|---|-----------------------|-------------|---|

***Note:** *separate ordering option is available*

**** Note:** *one of the mentioned tubes is delivered according to customer preferences*

*****Note:** *indication depends on the customer's country and is determined at order*

7 STORAGE

The device in manufacturer's package shall be stored indoors, in heated and ventilated room, at a temperature from 5 °C to +40 °C and relative humidity not more than 80 % (at a temperature of +25 °C).

In case of temporary withdrawal, the device shall be stored without manufacturer's packaging in storehouse at a temperature from 5 °C to +40 °C and relative humidity not more than 80 % (at a temperature of +25 °C). Devices shall be placed on a rack shelf in single line. Do not store the device in places containing acid-base vapors and vapors of other deleterious substances.

In case of long-term storage after use, the device shall be placed in hermetically sealed plastic bag and packed in manufacturer's packaging way to be protected against possible mechanical damage.

8 TRANSPORTATION

For transportation, pack the device in a hermetically sealed plastic bag and place it into a filling piece with the screen upward. Also pack device accessories in hermetically sealed plastic bags, power adapter - in a cardboard box, and place them in separate compartments of the filling piece.

Put the device and its accessories into cardboard box (consumer container), then put one more filling piece atop. Secure joints of the box with tape.

The device in the package can be transported by all types of covered vehicles, except non-heated compartments of aircrafts, in accordance with the rules of transportation valid for vehicle of this type.

Transportation conditions:

environmental temperature: -50 °C ...+50 °C.

9 DISPOSAL



CAUTION

After use, single-use supplies must be disposed of in accordance with the standards accepted by the medical institution.



For countries covered by Directive 2012/19/EU (WEEE):

The device is not intended for household use and is not subject to disposal with standard electrical and electronic equipment.

At the end of its service life and after it reached its limit state, the device, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. A limit state of the device is defined by its impossibility to perform the functions according to technical characteristics to reach its intended use. Before the device is sent for disposal, it is brought to a safe condition, cleaned and disinfected as described in p. 2.1.

Parts of electronic equipment must not be disposed as unsorted municipal waste and must be collected separately.

The battery must be disposed separately.

Packaging of the device and its accessories (including single use accessories) must be disposed of in accordance with the effective national standards and procedures which are applicable in a facility.

If you have questions concerning disposal of the product, please contact Triton Electronic Systems Ltd. or its representatives.

10 WARRANTY



CAUTION

Warranty service of the device failed because of incorrect operation is not performed.

CAUTION

The warranty does not cover defects or malfunction caused by liquid getting into the measuring cell of the device.

CAUTION

The warranty does not cover cable failure resulting from misuse.

These warranty obligations are general and apply to equipment produced by Triton Electronic Systems Ltd. sold and operated outside of the Russian Federation.

Manufacturer guarantees the compliance of the device with the requirements of TESM.943129.002 TR in case of normal, proper and intended transportation, storage and usage according to current user manual.

The warranty period of the new equipment is 12 months and it can be extended according to the contract. It is calculated from the commission date (date of putting into operation) by the service center authorized by Triton Electronics Systems Ltd. In the absence of a note of commissioning in this manual, the warranty period is calculated from the date of sale of the equipment under the supply agreement or, in the absence of an agreement, from the date of equipment manufacture specified on the equipment (see also section 12). In any case, the warranty period of operation cannot exceed 2.5 years from the date of equipment manufacture.

The limited warranty period, which is 12 months, is established for specific components that are subject to natural wear: batteries.

The warranty period for equipment repaired in an authorized service center is 6 months and is calculated from the repair end date specified in section 13 of this manual.

Warranty obligations do not apply to disposable consumables supplied with equipment. Complaints concerning them must be sent to the respective manufacturer. Also the warranty does not apply to the expiration of disposable consumables from the delivery set.

Warranty service is not provided for:

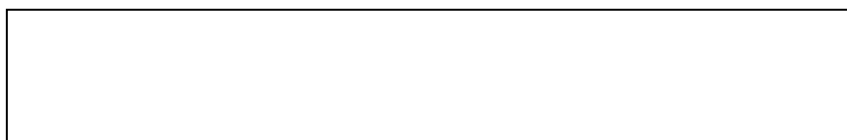
- not following the operating instructions stated in user manual;
- absence of the user manual or serial number on the equipment, as well as incomplete equipment;
- equipment malfunctions caused by impacts (falls), violation of the rules of packaging, storage and transportation, ingress of foreign objects or liquids, voltage drops or inconsistency with power supply standards and other similar external factors;

- faults caused by the use of non-recommended or low-quality spare parts and consumables;
- no mandatory periodic maintenance;
- detection of attempted repairs by persons and organizations not authorized by the manufacturer;
- normal wear and tear of accessories, spare parts and consumables.

Keep the transport packaging and user manual for the entire warranty period. Make sure that the commissioning and maintenance repair data are correct.

For free consultations concerning operation and maintenance please contact the manufacturer by phone +7 (343) 304-60-57 or local distributor in your region.

In case of event that the service center receives the warranty equipment that does not contain defects declared by the buyer, company reserves the right to charge payment for delivery, testing and after-sales service of the equipment.



The procedure for providing the warranty service

In order to use the warranty service, you need:

1. Note the following information:

- equipment name, serial number and date of manufacture (on the back of the equipment);
- commissioning date by a representative of an authorized service center (in section 13 of current manual or the commissioning act);
- the nature of the malfunction.

2. Contact Triton Electronics Systems Ltd. by phone. +7 (343) 304-60-57 or local distributor in your region.

3. To specify with a representative of the authorized service center nature of the manifestation of the malfunction. When confirming the malfunction, agree on procedure and terms of delivery of the equipment to service center or terms of service engineer's departure to the place of operation.

4. To deliver the equipment to a service center, assemble a complete delivery set of the equipment and pack it in order to avoid damage during transportation. It is preferable to use the equipment original package.

5. After delivery of the equipment to service center, you will be informed about the results of technical examination and the timing of receipt of the repaired equipment in case the case is recognized as a warranty.

11 CERTIFICATE OF ACCEPTANCE

Multigas Analyzer AMG-06, serial No. _____, Software kit No _____complies with the technical requirements TESH.943129.002 TR and considered suitable for operation.

Manufacturing date _____



QA representative _____ / _____ / QA stamp
signature name

12 COMMISSION DATE MARK

Commission date _____
Day, month, year

Operating organization (customer):

organization name

responsible representative, position, signature, name



Stamp place

Service organization (provider):

organization name

responsible representative, position, signature, name



Stamp place

13 MAINTENANCE AND REPAIR DATA

13.1 Device Maintenance (MA)

This section is filled by a representative of the service personnel or service organization. The frequency and order of maintenance are specified in section 4 of current manual.

| MA № | MA date | Organization, position, MA performer | Remarks, works performed | MA performer signature |
|------|---------|--------------------------------------|--------------------------|------------------------|
| | | | | |

13.2 Device Repair

| Repair date | Malfunction | Organization, position, repair performer | Works performed | Repair performer signature |
|-------------|-------------|--|-----------------|----------------------------|
| | | | | |

APPENDIX A. ELECTROMAGNETIC COMPATIBILITY

The device is intended for use in the electromagnetic environment specified below. It is recommended to use the device in the specified electromagnetic environment.

During operation, it is necessary to use the power cord supplied with the device.

Table A1 - Guidance and manufacturer's declaration – electromagnetic emissions

| Emissions test | Compliance | Electromagnetic environment – guidance |
|--|------------|---|
| RF emissions CISPR 11:2009 | Group 1 | The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11:2009 | Class A | The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. |
| Harmonic emissions IEC 61000-3-2:2005 | Class A | |
| Voltage fluctuations/ flicker emissions IEC 61000-3-3:95 +A1:2001 | Complies | |

Table A2 - Guidance and manufacturer's declaration – electromagnetic immunity

| IMMUNITY test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|---|---|---|--|
| Electrostatic discharge (ESD) IEC 61000-4-2:2008 | ± 8 kV contact ± 15 kV air | ± 8 kV contact ± 15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4:2012 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines ± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5:2005 | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2004 | <5 % U_T (>95 % dip in U_T) for 0,5 cycle <5 % U_T (>95 % dip in U_T) for 1 cycle 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s | <5 % U_T (>95 % dip in U_T) for 0,5 cycle <5 % U_T (>95 % dip in U_T) for 1 cycle 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |

APPENDIX A. ELECTROMAGNETIC COMPATIBILITY

| IMMUNITY test | IEC 60601 test level | Compliance level | Electromagnetic environment – guidance |
|--|-----------------------------|------------------|--|
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8:2009 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| <i>NOTE - U_T is the a.c. mains voltage prior to application of the test level.</i> | | | |
| Conducted RF IEC 61000-4-6:2013 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 12 \sqrt{P}$ |
| Radiated RF IEC 61000-4-3:2008 | 3 V/m 80 MHz to 2.7 GHz | 3 V/m | $d = 1.2 \sqrt{P}$ (80 MHz to 800 MHz); $d = 2.3 \sqrt{P}$ (800 MHz to 2.7 GHz), where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| a 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 be necessary, such as re-orienting or relocating the device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. | | | |

Table A3 - Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or 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 transmitter, W | Separation distance according to frequency of transmitter, m | | |
|--|--|---|--|
| | 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.20 | 1.20 | 2.30 |
| 10 | 3.80 | 3.80 | 7.30 |
| 100 | 12.00 | 12.00 | 23.00 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
 NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

APPENDIX B. PROTOCOL OF INFORMATION EXCHANGE WITH AN EXTERNAL MEDICAL INFORMATION SYSTEM

When connected to a Wi-Fi network, the device starts transmitting the measured values to an external medical information system. Data is transmitted in accordance with the standard ISO/IEEE 11073-20601.

A description of the information exchange protocol is sent to the consumer upon a separate request.

The parameters of the device wireless data transmission network are given in Table B1.

Table B1 - Wireless Data Network Settings

| | |
|--------------------|--|
| Standards | ISO/IEC/IEEE 8802-11 b/g/n |
| Frequency range | 2400 MHz to 2483.5 MHz |
| Operating Channels | 1 to 14 allowed channel range is in the legislation in the relevant countries |
| Operation mode | Station |
| Security | WEP/WPA/WPA2 |
| Safety distance | 10 m radius circle centered at the point of radius |
| Certificates | FCC/CE/TELEC/SRRC |
| Wi-Fi transmitter | Espressif ESP8266 (ESP-WROOM-02) |

APPENDIX C. INTERFERING GAS AND VAPOR EFFECTSTable C1 - Influence of the interfering gas on the measured value of CO₂

| Gas | Concentration (%) | Accuracy (%abs) |
|-------------|--------------------------|------------------------|
| Sevoflurane | ≤5 | 0.1 |
| Isoflurane | ≤5 | |
| Desflurane | ≤15 | 0.2 |
| Xenon | <100 | 0.1 |
| Helium | <50 | 0.1 |
| Ethanol | <0.1 | 0 |
| Acetone | <1 | 0.1 |
| Methane | <1 | 0.1 |

APPENDIX C. INTERFERING GAS AND VAPOR EFFECTS

Table C2 - Influence of the interfering gas on the measured value of the Multigas Analyzer

| Gas | Concentration (%) | Quantitative effect (%abs)* | |
|-----------------|-------------------------------|-----------------------------|-------------|
| | | CO ₂ | Anaesthetic |
| CO ₂ | ≤10 | / | 0.1 |
| Anaesthetic | within the measurement limits | 0 | / |
| Xenon | <100 | 0.1 | 0 |
| Helium | <50 | 0.1 | |
| Ethanol | <0.1 | 0 | |
| Aceton | <1 | 0.1 | |
| Methane | <1 | 0.1 | |

* – The maximum quantitative effect of each gas at concentrations within the specified error ranges for each gas. The total effect of all interfering substances usually does not exceed 5% of the gas concentration.

APPENDIX D. CALCULATION OF THE MAC COEFFICIENT DEPENDING ON THE AGE

For example, an expression to calculate correction for age for the 1MAC² is given below:

$$MAC_{age} = MAC_{40} \times 10^{-0.00269(age-40)} \quad (3.2)$$

Where MAC_{age} – the MAC coefficient that user can set in the “Settings 2” screen,

MAC_{40} - the 1MAC index for anaesthetics,

age – the patient age (the AMG-06 does not take it from the patient info).

In actual use, the MAC coefficient may consider an effect of age, weight, pressure, temperature and other factors. A user should calculate an appropriate MAC coefficient independently and type it in the “Settings 2” screen.

For example, patient age is 50 years, Etiso value is 3%, anaesthetic type is isoflurane and 1MAC is 1.15%, then substitute the values in the expression 3.2:

$$MAC_{age} = 1.15 \times 10^{-0.00269(50-40)} = 1.08.$$

In this case, in the “Monitoring” screen the MAC index will be displayed calculated based on the expression 3.1:

$$MAC = \frac{3}{1.08} = 2,78.$$

Below see table with the MAC coefficient dependency from patient age for the three types of anaesthetics. The table contain calculation for age from 3 to 115. For further ages please calculate accordingly.

² BJA British Journal of Anaesthesia, September 2003, Age-related iso-MAC charts for isoflurane, sevoflurane and desflurane in man, R. W. D. Nickalls and W. W. Mapleson

APPENDIX D. CALCULATION OF THE MAC COEFFICIENT DEPENDING ON THE AGE

Table D1 - Examples of calculations of the MAC coefficient values depending on the age based on the expression 3.2

| Age | Isoflurane | Sevoflurane | Desflurane |
|-----|------------|-------------|------------|
| 3 | 1.45 | 2.64 | 7.55 |
| 4 | 1.44 | 2.62 | 7.50 |
| 5 | 1.43 | 2.61 | 7.45 |
| 6 | 1.42 | 2.59 | 7.41 |
| 7 | 1.41 | 2.58 | 7.36 |
| 8 | 1.40 | 2.56 | 7.32 |
| 9 | 1.39 | 2.54 | 7.27 |
| 10 | 1.38 | 2.53 | 7.23 |
| 11 | 1.38 | 2.51 | 7.18 |
| 12 | 1.37 | 2.50 | 7.14 |
| 13 | 1.36 | 2.48 | 7.09 |
| 14 | 1.35 | 2.47 | 7.05 |
| 15 | 1.34 | 2.45 | 7.00 |
| 16 | 1.33 | 2.44 | 6.96 |
| 17 | 1.33 | 2.42 | 6.92 |
| 18 | 1.32 | 2.41 | 6.88 |
| 19 | 1.31 | 2.39 | 6.83 |
| 20 | 1.30 | 2.38 | 6.79 |
| 21 | 1.29 | 2.36 | 6.75 |
| 22 | 1.29 | 2.35 | 6.71 |
| 23 | 1.28 | 2.33 | 6.67 |
| 24 | 1.27 | 2.32 | 6.63 |
| 25 | 1.26 | 2.30 | 6.58 |
| 26 | 1.25 | 2.29 | 6.54 |
| 27 | 1.25 | 2.28 | 6.50 |
| 28 | 1.24 | 2.26 | 6.46 |
| 29 | 1.23 | 2.25 | 6.42 |
| 30 | 1.22 | 2.23 | 6.38 |
| 31 | 1.22 | 2.22 | 6.34 |
| 32 | 1.21 | 2.21 | 6.30 |
| 33 | 1.20 | 2.19 | 6.27 |
| 34 | 1.19 | 2.18 | 6.23 |
| 35 | 1.19 | 2.17 | 6.19 |
| 36 | 1.18 | 2.15 | 6.15 |
| 37 | 1.17 | 2.14 | 6.11 |

| Age | Isoflurane | Sevoflurane | Desflurane |
|-----|------------|-------------|------------|
| 38 | 1.16 | 2.13 | 6.07 |
| 39 | 1.16 | 2.11 | 6.04 |
| 40 | 1.15 | 2.10 | 6.00 |
| 41 | 1.14 | 2.09 | 5.96 |
| 42 | 1.14 | 2.07 | 5.93 |
| 43 | 1.13 | 2.06 | 5.89 |
| 44 | 1.12 | 2.05 | 5.85 |
| 45 | 1.11 | 2.04 | 5.82 |
| 46 | 1.11 | 2.02 | 5.78 |
| 47 | 1.10 | 2.01 | 5.75 |
| 48 | 1.09 | 2.00 | 5.71 |
| 49 | 1.09 | 1.99 | 5.67 |
| 50 | 1.08 | 1.97 | 5.64 |
| 51 | 1.07 | 1.96 | 5.60 |
| 52 | 1.07 | 1.95 | 5.57 |
| 53 | 1.06 | 1.94 | 5.54 |
| 54 | 1.05 | 1.93 | 5.50 |
| 55 | 1.05 | 1.91 | 5.47 |
| 56 | 1.04 | 1.90 | 5.43 |
| 57 | 1.04 | 1.89 | 5.40 |
| 58 | 1.03 | 1.88 | 5.37 |
| 59 | 1.02 | 1.87 | 5.33 |
| 60 | 1.02 | 1.86 | 5.30 |
| 61 | 1.01 | 1.84 | 5.27 |
| 62 | 1.00 | 1.83 | 5.24 |
| 63 | 1.00 | 1.82 | 5.20 |
| 64 | 0.99 | 1.81 | 5.17 |
| 65 | 0.99 | 1.80 | 5.14 |
| 66 | 0.98 | 1.79 | 5.11 |
| 67 | 0.97 | 1.78 | 5.08 |
| 68 | 0.97 | 1.77 | 5.04 |
| 69 | 0.96 | 1.75 | 5.01 |
| 70 | 0.95 | 1.74 | 4.98 |
| 71 | 0.95 | 1.73 | 4.95 |
| 72 | 0.94 | 1.72 | 4.92 |
| 73 | 0.94 | 1.71 | 4.89 |
| 74 | 0.93 | 1.70 | 4.86 |
| 75 | 0.93 | 1.69 | 4.83 |

APPENDIX D. CALCULATION OF THE MAC COEFFICIENT DEPENDING ON THE AGE

| Age | Isoflurane | Sevoflurane | Desflurane |
|-----|------------|-------------|------------|
| 76 | 0.92 | 1.68 | 4.80 |
| 77 | 0.91 | 1.67 | 4.77 |
| 78 | 0.91 | 1.66 | 4.74 |
| 79 | 0.90 | 1.65 | 4.71 |
| 80 | 0.90 | 1.64 | 4.68 |
| 81 | 0.89 | 1.63 | 4.65 |
| 82 | 0.89 | 1.62 | 4.63 |
| 83 | 0.88 | 1.61 | 4.60 |
| 84 | 0.88 | 1.60 | 4.57 |
| 85 | 0.87 | 1.59 | 4.54 |
| 86 | 0.86 | 1.58 | 4.51 |
| 87 | 0.86 | 1.57 | 4.48 |
| 88 | 0.85 | 1.56 | 4.46 |
| 89 | 0.85 | 1.55 | 4.43 |
| 90 | 0.84 | 1.54 | 4.40 |
| 91 | 0.84 | 1.53 | 4.37 |
| 92 | 0.83 | 1.52 | 4.35 |
| 93 | 0.83 | 1.51 | 4.32 |
| 94 | 0.82 | 1.50 | 4.29 |
| 95 | 0.82 | 1.49 | 4.27 |

| Age | Isoflurane | Sevoflurane | Desflurane |
|-----|------------|-------------|------------|
| 96 | 0.81 | 1.48 | 4.24 |
| 97 | 0.81 | 1.48 | 4.22 |
| 98 | 0.80 | 1.47 | 4.19 |
| 99 | 0.80 | 1.46 | 4.16 |
| 100 | 0.79 | 1.45 | 4.14 |
| 101 | 0.79 | 1.44 | 4.11 |
| 102 | 0.78 | 1.43 | 4.09 |
| 103 | 0.78 | 1.42 | 4.06 |
| 104 | 0.77 | 1.41 | 4.04 |
| 105 | 0.77 | 1.40 | 4.01 |
| 106 | 0.76 | 1.40 | 3.99 |
| 107 | 0.76 | 1.39 | 3.96 |
| 108 | 0.75 | 1.38 | 3.94 |
| 109 | 0.75 | 1.37 | 3.91 |
| 110 | 0.75 | 1.36 | 3.89 |
| 111 | 0.74 | 1.35 | 3.87 |
| 112 | 0.74 | 1.34 | 3.84 |
| 113 | 0.73 | 1.34 | 3.82 |
| 114 | 0.73 | 1.33 | 3.79 |
| 115 | 0.72 | 1.32 | 3.77 |