# AIRone - Instructions For Use

OperationAIR

Version 1.5, April 22, 2020



⚠️ <span style="color:red">WARNING:</span>
The device should only be used by trained users and these instructions should be thoroughly read before use.

Device version: 1.0
Firmware version: 1.0
Manual version: 1.5

# Liability and warranty

This medical device is being made available to healthcare institutions in the Netherlands which have explicitly requested this on the basis of the procedure established by the IGJ (Inspection for Healthcare and Youth) to deliver non-CE-certified medical devices or devices which have not undergone the normal assessment procedure. Delivery of this medical device has happened on the request from the healthcare institution and the application of this medical device is based on the responsibility of the healthcare institution as defined in the 'Wet kwaliteit, klachten en geschillen zorg (Wkkgz)'. The manufacturer has reported the issue of this device to the IGJ conform aforementioned procedure.

# Customer support

If the product fails to function or when service, assistance or recalibration is needed, please contact:

OperationAIR
Mekelweg 2
2628 CD Delft
The Netherlands

Phone (service):
Phone (emergency):
Email:
Online:                    operationair.org

# Contents

# 1   Introduction

The AIRone is an automatic ventilator for the treatment of patients in respiratory distress. The primary objectives of automatic ventilation are oxygenation, elimination of $CO_2$ and taking over the breathing effort for the patient without continuous human intervention.

## 1.1   Intended use

The AIRone provides positive-pressure ventilation (PPV) for emergency automatic ventilation with adjustable positive end-expiratory pressure (PEEP), I:E ratio, peak pressure, oxygen concentration(%) and breathing frequency, created for the use on adult (suspected) COVID-19 patients who need non-weaned respiratory support to bridge a longer period of time until conventional ventilation becomes available.

## 1.2   Intended user

The AIRone should only be used by professional healthcare providers who are experienced in ventilation treatment, and have received training in the use of the AIRone ventilator.

## 1.3   Intended patient

The AIRone is intended to treat COVID-19 patients in acute respiratory distress, who are in need of mechanical ventilation. Patients should be intubated and kept in medically induced coma.

## 1.4   Contra-indications

- Pediatric patients

## 1.5   Side effects

The side effects that can occur when mechanically ventilating a patient are:

- Infection

- Irritation of the throat or lungs

- Vocal cord issues

- Lung injury

# 2   Warnings

⚠ The AIRone should ONLY be used when absolutely needed and no conventional ventilation equipment is available.

⚠ The AIRone may only be used by trained users.

⚠ The AIRone is not able to preform assisted breath initiated by a patient-trigger event, and should therefore ONLY be used to bridge the period from ICU intake until a conventional ventilation machine is available.

⚠ Always perform a Pre-use Check before connecting the ventilator to a patient.

⚠ Do not use the device when it is visibly damaged.

⚠ Discontinue the device when the user-interface shows unfamiliar warnings, when alarms cannot be resolved, or in the case of unfamiliar or unexpected behaviour.

⚠ When connected to a patient:
  - Do not leave the patient unattended
  - Continuously monitor the device and the patient
  - Do not disconnect any hoses or connectors

⚠ Manual backup ventilation must be available at all times.

⚠ Any serious adverse events must be reported to service@operationAIR.org

⚠ Keep the system and its gas hoses clear of all ignition sources.

⚠ Do not use the system with worn or frayed hoses or hoses that have been contaminated by combustible materials such as grease or oil.

⚠️ Oxygen-enriched gas is extremely flammable:  if you detect a burning odor, disconnect the oxygen supply to the ventilator and turn off the device.

⚠️ The pressure sensor is (like most ventilator machines) positioned at the device-end of the expiratory tube, due to a pressure decay over the inspiratory tube, the pressure delivered to the patient is 3-5 $cmH_2O$ lower than the value set on the Graphical User Interface (GUI).

⚠️ When changing the $FiO_2$, it will take some time before the $FiO_2$ in the inspiratory air will change.

⚠️ To avoid the risk of electric shock, the AIRone must only be connected to a supply mains with protective earth.

⚠️ Be careful with the alarm limit settings and do not set the alarm limits at extreme values, this can render the alarm system useless.

# 3 Product description

## 3.1 Product



Figure 1: The frontview of the exterior of the AIRone. The numbers are explained below.

Figure 2: The backview of the exterior of the AIRone. The numbers are explained below.

1. Oxygen air input port
2. Compressed air input port

3. Additional grounding

4. Cable hook

5. Power supply unit

6. Graphical User Interface (GUI)

7. Patient-connection port (Inspiratory tube)

8. Patient-connection port (Expiratory tube)

## 3.2 Graphical User Interface

⚠ The user interface described in this section is currently under construction and not definitive yet

The user interface consists of a touchscreen with multiple tabs. The main interface is shown below in figure 3 and 4. Different parameters and graphs are shown in this window.
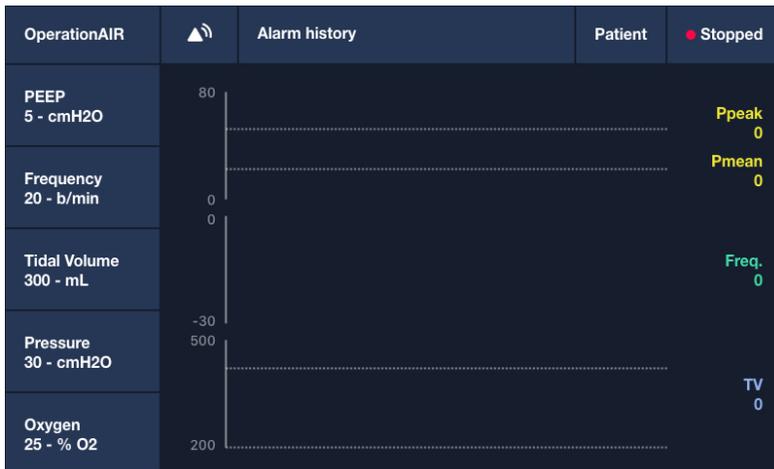


Figure 3: The main interface of the AIRone when not in ventilation mode.
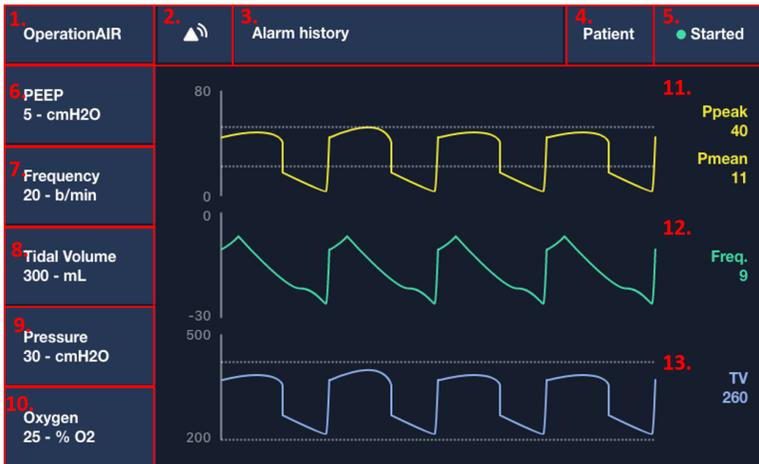
Figure 4: Het hoofdscherm van de gebruikersinterface tijdens beademing met de AIRone

The functionalities of the different tabs are numbered in figure 4 and will be explained in the subsections below.

1. Tab general settings

2. Alarm priority symbol

3. Tab alarm history

4. Patient data tab

5. Start/stop button

6. PEEP value

7. Settings for breathingfrequency

8. Tidal volume

9. Settings pressure

10. Settings $FiO_2$

11. Flow graph

12. Druk graph

### 3.2.1   Tab general settings

In this tab, the brightness of the screen and the current time can be set. Also, the leak test, that needs to be executed before using the AIRone,is started in this tab.

### 3.2.2   Alarmsymbol
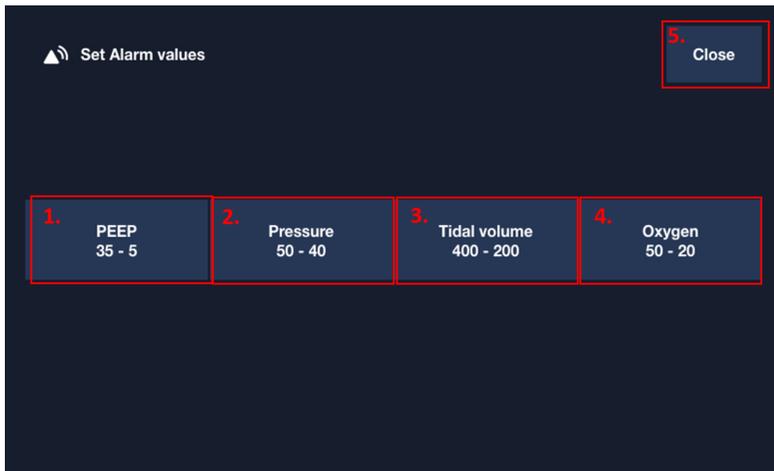


Figure 5: Tab with the different alarms in which the alarm limits can be set

1. Settings alarm limits PEEP

2. Settings alarm limits pressure

3. Settings alarm limits FiO$_2$

4. Close this tab and return to the main interface

The interface for setting the alarm limits for PEEP is shown below in figure 6.
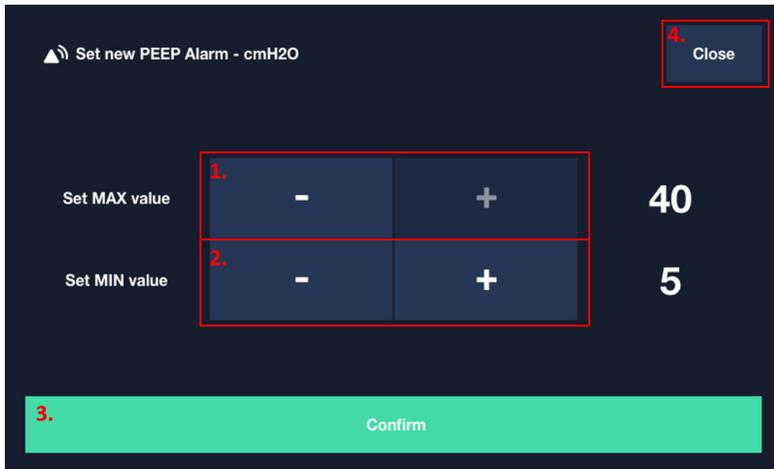
Figure 6: Tabblad PEEP instellingen.

In this tab, the limits can be set by pressing the plus or minus symbol.

1. Set the maximum PEEP value

2. Set the minimum PEEP value

3. Confirm the settings

4. Close this tab and return to the main interface

### 3.2.3 Tab alarmhistory
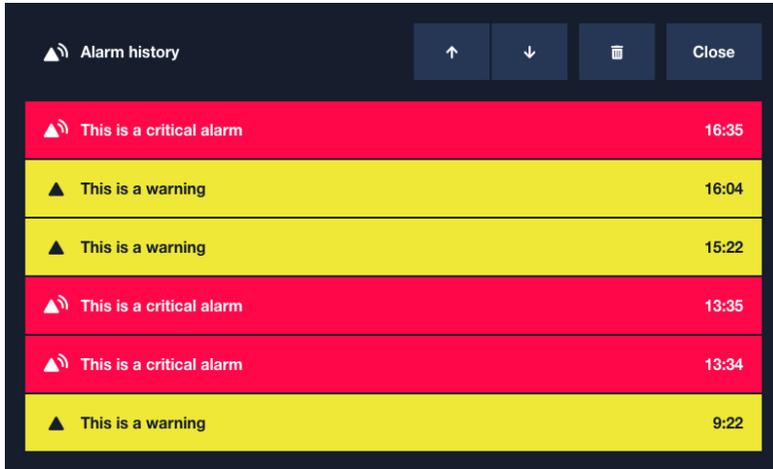


Figure 7: Example of the alarm history tab

### 3.2.4 Tab patient data
The patient data tab is shown below. In this tab, flow pressure and tidal volume curves of the past can be seen.

### 3.2.5 Start/stop button
The ventilation can be started and stopped with this button on the top right of the main interface.

in this tab. There are two variation of this tab. When the ventilation is stopped, figure **??** will appear with the option if you want to start the ventilation. When the ventilation is started, figure **??** will appear with the option to stop the ventilation.

### 3.2.6 Settings for breathing frequency
The breathing frequency and inspiratory expiratory ratio can be set in this tab.
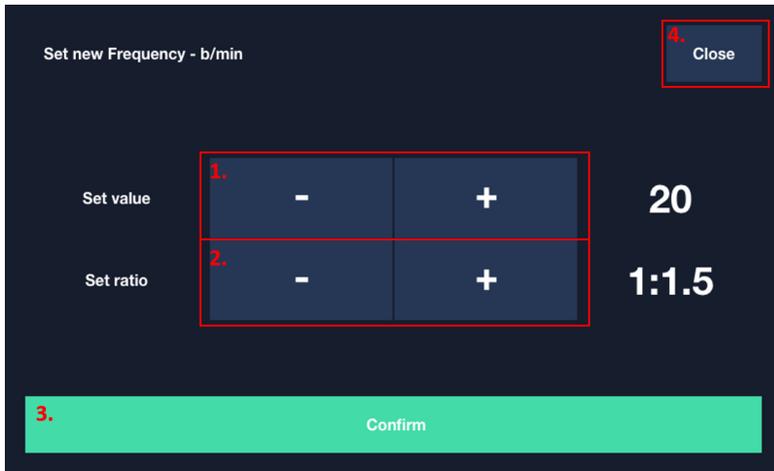
Figure 8: Tab breathingfrequency settings.

1. Set breathing frequency

2. Set the I:E ratio

3. Confirm these settings

4. To return to the main interface, press close.

**3.2.7   Settings pressure**

**3.2.8   Settings FiO$_2$**

# 4   Product specifications

| Productspecifications | |
|---|---|
| Tidal volume | 5- 700 mL |
| Pressure above PEEP | 5-40 cmH$_2$O |
| Positive end expiration pressure (PEEP) | 5-30 cmH$_2$O |
| Maximum pressure | 70 cmH$_2$O |
| Breathing-frequency | 5-40 b/min |
| Inspiration expiration ratio (I:E) | 1:1 - 1:3 |
| Peak inspiration flow | 0-100 L/min |
| Pressure rise time, inspiration rise time | 0.3-0.7 sec |
| O$_2$-concentration FiO$_2$ | 21-100 % |
| Mass flow controllers | Accuracy: ± 1 % FSS |
| | Max output flow: 50 l/min |
| Displayed | flow and pressure |
| Weigth | 24.3 kilogram |

Table 1: Productspecifications of the AIRone ventilator.

| Electrical properties | |
|---|---|
| Input voltage | 230-240 V AC |
| Input frequency | 50-60 Hz |
| Isolation | Class I |
| Compliance | IEC 60601-1-2 |
| Battery duration | 30-45 minutes |

Table 2: Electrical properties.

| Operating conditions | |
|---|---|
| Environment temperature | 15-25 degrees Celsius |
| Relative humidity | 10-90% |
| Atmospheric pressure | 0.995-1.05 bar |

Table 3: Operating conditions.

# 5 Installation

## 5.1 Disposables

The disposables needed for full functionality of the AIRone that are not provided by OperationAIR are:

- The hoses with NIST connection for connecting the AIRone to the compressed air and oxygen infrastructure of the hospital should be in-house available.

- Heat and Moisture Exchanger (HME) filter

- High-efficiency particulate air (HEPA) filter

- Inspiratory and expiratory tubes for the connection of the AIRone to the patient

- Endotracheal tube

The intubation set, consisting of an endotracheal tube and the devices and anaesthetics needed to intubate the patient should also be in-house available.

The inspiratory and expiratory tubes connected to the HEPA and HME filter will later on be called "breathing circuit". Instructions for connection of these components is described below in the subsection set and start ventilation.

## 5.2 Breathing modes

Ventilation using the AIRone is pressure-controlled and forced. It is not possible to synchronise with spontaneous breathing of the patient. The start and end of the inspiration is determined by the AIRone, based on values specified by the user. Therefore, no spontaneous breathing tests are available and no back-up respiratory rate (i.e. a very low respiratory rate to allow intermittent spontaneous breathing) are possible.

## 5.3 Installation

1. Set the AIRone-ventilator in the desired position.

2. Use the brakes placed on the bottom of the trolley.

3. Connect the oxygen and compressed air hose to the AIRone via the NIST-connections.

4. Connect the oxygen and compressed air hose to the local gas network.

5. Connect the grounding cable

6. Connect the power supply cable to the main power supply.

## 5.4   Pre-use checks

⚠ The AIRone is not capable of self testing before use

Before the patient is connected to the AIRone-ventilator, the following control tests need to be done.

**Pre-use checks** include tests and measurements of:

- Internal technical functionality
- Check if the AIRone is plugged

**The internal technical functionality**

1. Start the AIRone ventilator via the on/off-button at the power supply module.

2. Check if all parameters can be changed and if the alarms are working by changing the alarm limits

3. Check if the desired $FiO_2$ can be reached.

# 6 Operation

The AIRone-ventilator must be installed as described in section 5: Installation. Before starting the procedure, check the unit, trolley, sensors, cables, connections and perform the pre-use checks described in subsection 5.4. Do not use a damaged device.

## 6.1 Set and start ventilation

⚠ Before preparing the patient for intubation, be sure the AIRone ventilation system is working correctly by executing the pre-use checks.

1. Place the HEPA filter between the end of the expiratory tube and entry of the AIRone ventilator.

2. Attach the inspiratory and expiratory tubes to the AIRone-ventilator.

3. Place the HME filter at the end of the inspiratory tube.

4. Turn on the AIRone via the on/off-button at the power supply module.

5. Perform the pre-use checks

6. Select the desired ventilator settings using the touchscreen (see subsection 6.3).

7. Select the desired alarm limits using the touchscreen (see subsection 6.3).

8. Intubate patient and connect the endotracheal tube to the breathing circuit (inspiratory and expiratory tubes with the filters) following the in-house protocol.

9. Start ventilation by pressing start in the tab on the top right of the touchscreen.

10. Check if the HME-filter and the HEPA-filter are placed correctly.

11. Evaluate the flow- and pressure curves and observe the patient.

12. Evaluate the position of the endotracheal tube.

13. If necessary, optimise the ventilator settings based on patient observation and clinical parameters.

## 6.2   Disconnection

⚠ The device needs to be shut down before unplugging the energy supply.

The AIRone needs to be disconnected from the patient if there is a conventional ventilation machine available, if the patient gets better and when the patient dies. The steps that need to be taken when disconnecting the AIRone from the patient are described below. The cleaning protocol for the AIRone-ventilator is described extensively in section 9.

### 6.2.1   Disconnection (Transfer to a conventional ventilator)

1. Prepare the conventional ventilator following the instructions of the ventilator.

2. Prepare patient for switching to a conventional ventilator according to the in-house protocol.

3. Disconnect the AIRone breathing circuit from the endotracheal tube.

4. Discart disposables with the medical waste following the in-house protocol.

5. Connect the endotracheal tube to the breathing circuit connected to the conventional ventilator and start ventilation.

6. Stop ventilation on the AIRone by pressing the "Stop"-button for 5 seconds.

7. Shut down the software by pressing the "shut down"-button in the "Menu" tab.

8. Turn the AIRone off via the on/off-button on the power supply module.

9. Disconnect the power supply cable

10. Disconnect the grounding cable

11. Disconnect the oxygen and compressed air hoses from the AIRone and local gas network

12. Clean AIRone-ventilator according to the instructions in section 9 of this manual.

### 6.2.2   Disconnection (patient died)

1. Disconnect the patient from the AIRone by disconnecting the breathing circuit and extubating the patient.

2. Discard the disposables with the medical waste following in-house protocol.

3. Stop ventilation by pressing the "Stop"-button for 5 seconds.

4. Shut down the software by pressing the "Shut down"-button in the "Menu"tab.

5. Turn AIRone off via the on/off-button on the power supply module.

6. Disconnect the power supply cable

7. Disconnect the grounding cable

8. Disconnect oxygen and compressed air hoses from AIRone and the local gas network.

9. Clean AIRone-ventilator according to the instructions in section 9 of this manual.

## 6.3   Settings

The following parameters can be set:

- PEEP [cmH$_2$O]
- Breathing frequency [b/min]
- inspiratory, expiratory ratio [I:E ratio]
- FiO$_2$

For further instructions on how to set these parameters, see subsection 3.2.

# 7   Alarms and notifications

The alarm limits can be set as described in subsection 3.2. There are multiple alarms, these can be turned of by the user. Alarms that went off are saved in the tab alarm history.
The AIRone has the following alarms:

- Low pressure

- High pressure

- Low FiO$_2$ ($\geq$ 5 min)

- High FiO$_2$ ($\geq$ 15 min)

- Low PEEP

- Small tidal volume

- Large tidal volume

- Uses battery power

- Battery running low

## 7.1 Notifications and symbols

The symbol that appears when an alarm is going off is shown below in figure 9.

Figure 9: Notification symbol of an alarm (IEC 60417-5308)

# 8 Maintenance

In this section the general guideline for maintenance is given. For the disposables that are not provided by OperationAIR, the guidelines of the manufacturer should be followed. To reassure the safety and reliability of the device, the user must follow the maintenance procedure.

⚠ Maintenance may only be executed by OperationAIR certified maintenance personnel.

⚠ If the HEPA filter was not replaced in time or not used during ventilation, call the OperationAIR maintenance servicecenter.

⚠ Before opening the AIRone for maintenance of the interior, always be sure the AIRone is turned off and the power supply cable is unplugged.

**Replacements inbetween patients**

- HEPA filter

- HME filter

- Disposable tubes and hoses
- 3D-printed materials in the flowstream

**Yearly maintenance**

- General calibration
- General performance

| Interval | Part | Procedure |
|---|---|---|
| Inbetween patients | Disposables | The disposable tubes, hoses, HEPA and HME filters need to be replaced inbetween patients |
| | Battery | Check if battery is fully charged, if not, charge the battery for at least four hours by connecting the AIRone to the main energy supply |
| | All 3D-printed material in the flowstream | All 3D-printed materials in the flowstream should be inspected and replaced if necessary |
| Yearly | General calibration | Test using a test lung with sensors |
| | General performance | |

Table 4: Maintenance: overview of replacements.

The AIRone ventilator may not be disposed by the institution. When the AIRone is out of use or damaged, please contact service@operationair.org and follow further instructions.

# 9 Cleaning and desinfection

⚠️Do not use detergents containing abrasive components when cleaning and desinfecting the AIRone.

⚠️Do not use detergents with a chlorine concentration higher than 10.000 ppm or 1%.

⚠️Do not use detergents containing acetone when cleaning and desinfecting the touchscreen.

⚠️Do not use detergents containing alcohol at temperature higher than 60 degrees Celsius when cleaning and desinfecting the AIRone.

⚠️Do not clean the inside of the AIRone. This could damage to the internal components.

⚠️Follow the in-house protocol for cleaning and desinfection of devices that have been in contact with COVID-19 patients.

## 9.1 General

For cleaning and disinfection, the in-house protocols for cleaning medical equipment must be followed. The power supply, gas supply hoses and disposable components must be disconnected from the AIRone before cleaning. Too much water around electrical connections should be avoided. Excess water should be removed so that no liquid penetrates into the material. During cleaning and disinfection, avoid contamination by changing cloths and gloves after cleaning dirty surfaces. Cleaning should be done from top to bottom, from the cleanest to the dirtiest part and with non sterile gloves.

## 9.2 Cleaning

All components of the AIRone should be cleaned after each use and if there is visible contamination. The cleaning should be done with an impregnated disposable cloth or a cleaning cloth with a soap solution consisting of warm water with medical soap or a mild detergent. Table 5 gives an overview of the parts to be cleaned.

### 9.2.1 Instructions for cleaning

1. Check if power supply, oxygen and compressed air hoses and disposables are disconnected. If not, disconnect them first.

2. Use an impregnated disposable disposable cloth or clean cloth with soap solution (mild all-purpose cleaner, medical soap, etc.).

3. Clean outside of AIRone, from 'clean' to 'dirty' and from the top down. Replace cleaning cloth or gloves in between if necessary.

4. Allow the surface to air dry or use a suitable drying cloth.

5. Inspect all components and replace or report if necessary.

## 9.3 Desinfection

Desinfection should be done in case of visible contamination with body fluids or isolation measures, according to the in-house protocol. Before desinfection is started, cleaning is required. Desinfection can be done with a medical desinfectant (chlorine 70 %, chlorine solutions 250-1000 ppm, etc.). Table 5 gives an overview of the components to be desinfected.

### 9.3.1 Instructions for desinfection

1. Check if power supply, oxygen and compressed air hoses and disposables are disconnected. If not, disconnect them first.

2. Before disinfection is started, clean the AIRone.

3. Moisture the surface with a medical desinfactant (alcohol 70 %, chlorine solution, etc.)

4. Allow the surface to air dry.

5. Inspect all components and replace or report if necessary.

| Part | Frequenty | Cleaning | Disinfection |
|---|---|---|---|
| Exterior | Inbetween patients* | Yes | Yes |
| Inspiration and expirationtubes | Follow in-house protocol | Yes | Yes |
| Oxygen and air tubes | Follow in-house protocol | Yes | Yes |
| NIST connections | Inbetween patients* | Yes | Yes |
| Trolley | Inbetween patients* | Yes | Yes |
| Touchscreen | Inbetween patients* | Yes | Yes |

Table 5: Overview components to be cleaned.

*Sooner if visibly contaminated.

## 10 General safety instructions

- No smoking near the AIRone ventilator.

- Prohibited to sit, stand on or lean against the ventilation machine.

- The AIRone ventilator is not intended to use during transport.

- The AIRone ventilator should be unplugged and switched off when damage is suspected. i.e. after a fall or when other parts are visibly damaged.

- Before use, verify correct connection of the grounding cable.

- The battery is intended for backup and not for primary energy supply.

- It is not advised to use the AIRone ventilator in pediatric patients.

- Use the breaks when the device is not being moved.

## 10.1 Symbols

Safety symbols and their explanation.



Figure 10: Read the instructions for use



Figure 11: Prohibited to throw away the AIRone ventilator. Contact OperationAIR for instructions on returning the AIRone.



Figure 12: incendiary



Figure 13: Do not stand, sit, lean on or push the AIRone.

# 11 Troubleshooting

⚠ Always check the entered limits of the alarms.

| Alarm | Cause | Remedy |
|---|---|---|
| AIRone uses battery | The power cable is disconnected | Connect the AIRone to the main power supply |
| Battery almost empty | Battery used for too long | Connect the AIRone to the main power supply |
| Plateau pressure too high | Hardware or software problem | Switch patient to another ventilation machine and call the OperationAIR service number |
| Low tidal volume | Hardware problem, | Switch patient to another ventilation machine and call the OperationAIR service number |

| | Software problem, | Check the $O_2$-saturation of the patient. If sufficient, call the OperationAIR service number. If insufficient, switch patient to another ventilation machine and then call the OperationAIR service number. |
|---|---|---|
| | Tube problem | Check the tubes for hitches |
| PEEP too high | Hardware problem, | Switch patient to another ventilation machine and call the OperationAIR service number. |
| | Software problem, | Check the $O_2$-saturation of the patient. If sufficient, call the OperationAIR service number. If insufficient, first switch patient to another ventilation machine and call then the OperationAIR service number. |
| | Tube problem | Check the tubes for hitches |
| Low expiratory minute volume | Hospital oxygen infrastructure is insufficient | Connect oxygen tanks and follow the in-house protocol |
| Low FiO$_2$ ($\geq$ 5 min) | Hardware problem, | Switch patient to another ventilation machine and then call the OperationAIR service number. |
| | Software problem, | Check the $O_2$-saturation of the patient. If sufficient, call the OperationAIR service number. If insufficient, first switch patient to another ventilation machine and then call the OperationAIR service number. |
| Low plateau pressure | Hardware problem | Switch patient to another ventilation machine and call the OperationAIR service number. |
| Low PEEP | Hardware problem | Switch patient to another ventilation machine and call the OperationAIR service number |
| High FiO$_2$ ($\geq$ 15 min) | Hardware problem, | Switch patient to another ventilation machine and call the OperationAIR service number. |

| | | |
|---|---|---|
| | Software problem, | Check the $O_2$-saturation of the patient. If sufficient, call maintenance. |
| | | If insufficient, switch patient to another ventilation machine and call the OperationAIR service number. |

# 12 Classifications

## 12.1 MDR classification

| | |
|---|---|
| Classification to 2017/745 | Class IIb |
| Directives | Medical Device Directive 2017/745 annex VIII. |