**INSTRUCTION FOR USE (IFU)**
**INCLUDING DECLARATION OF CONFORMITY**


# ADS *eco*

## ADS – Anti-Decubitus-System to prevent bed sores

AirMed PLUS® is a registered mark of AirMed PLUS GmbH


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# Content

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|  | Please read the instructions carefully and especially pay attention to the sections marked with:  |

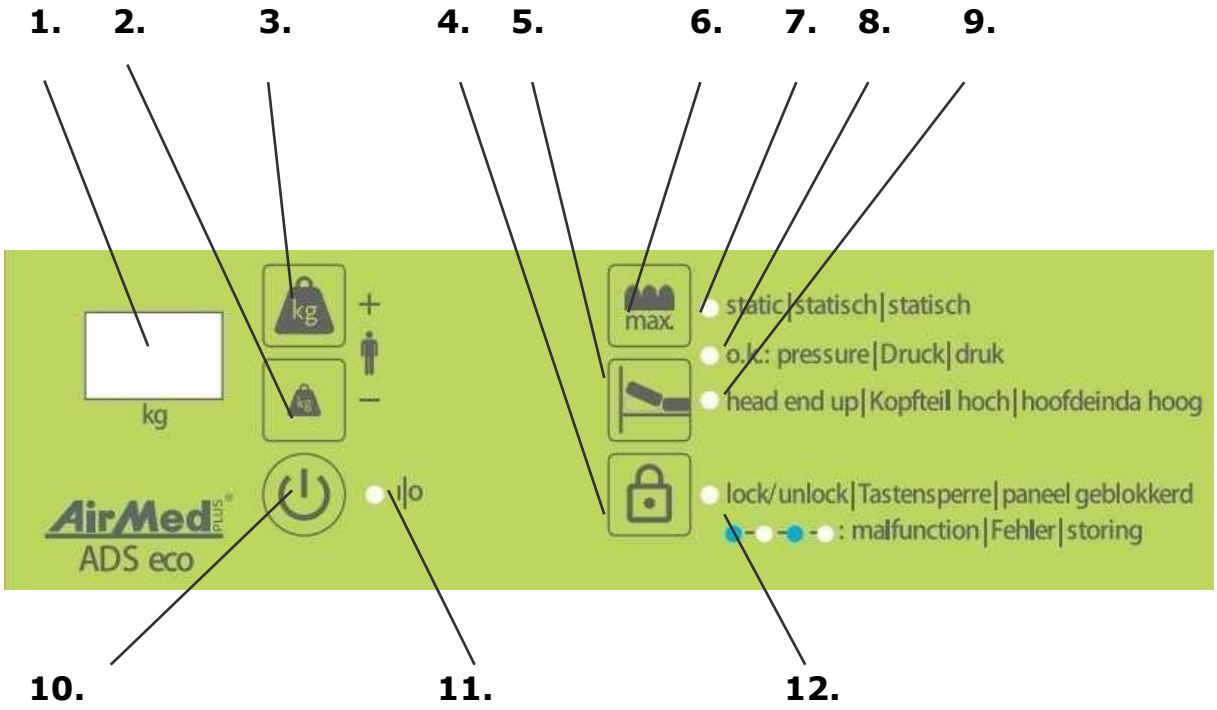
# Product description

The *ADS eco* is a medical device which provides support for 'functional static therapy[1]', alternating pressure positioning and nursery mode of patients for the purpose of decubitus prophylaxis and decubitus therapy. For this purpose, the *ADS eco* is connected to a special type of AirMed PLUS patient support/ mattress. The *ADS eco* is a microprocessor controlled device with an active pressure control and keeps the pressure in the air cells constant in relation to the set patient weight. The device with the corresponding mattress can be used for patients with pressure ulcers up to gradation 4.

[1] Functional Static Therapy = all cells have the same pressure. The cells are not pumped up too hard, but set accordingly on basis of the set weight of the patient. The patient is optimally lowered, and is available for treatment in therapeutic mode.

# Product images

## Front view



# Explanation of the symbols

Front view:

1. Display shows the chosen/set patient weight
2. Button to decrease the internal pressure of the mattress for a lower patient weight
3. Button to increase the internal pressure of the mattress for a higher patient weight
4. Button for locking and unlocking the panel to avoid unintended use
5. Button for increasing the pressure temporarily for approximately 25 Minutes when the bed will be lifted up
6. Button for "nursery mode": When pushed the mattress gets as hard as possible to lift up the patient (ATTENTION: "Nursery mode" will not turn off automatically)
7. LED is illuminated when mattress is in static mode
8. LED is permanently illuminated when pressure is "okay". When LED is flashing it shows that mattress is alternating pressure at that moment.
9. LED is illuminated when button number five is pressed to increase the pressure because head-end has been lifted up
10. Button to enable or disable the pump (function can be blocked when panel is locked)
11. LED is illuminated when the pump is enabled
12. Blue LED is flashing to indicate a problem. Be aware that it will be flashing when the mattress is being inflated to reach set pressure.
    It is permanently illuminated when panel is locked.

# Operating the device

## Connecting the device to the power supply.

The *ADS eco* must connect to a power strip of 230 V/50Hz to operate. Other voltages or frequencies are not allowed, it can lead to damage of the device.

## Connecting an AirMed PLUS mattress to the device

For the operating of the *ADS eco*, an AirMed PLUS patient's mattress must be connected. See chapter "Turning on the device" for instructions. The *ADS eco* offers specially adapted pressure protocols, which contain parameters to set the pressure value of the mattresses exactly, in order to ensure optimal pressure relief. Other types of patient mattresses from manufacturers other than listed are not allowed and should not be used in combination with the *ADS eco*.

Connecting the mattress to the *ADS eco* is made via the triple pneumatic encrypted plug at the bottom of the pump.

To the three hose connector plugs, on the mattress side, black O-rings for sealing are provided. To connect the mattress to the device (pump) check the O-rings for each connection. Three O-rings in total should be available and undamaged. You can order the O-rings at the service center as a replacement part (item number "99-1131eco"). Make sure all hoses are securely connected to the pneumatic plug. For attaching, you press pneumatic connector into the female part of the pump till it clamps, "clicks".

At a normal connection without pressing the clamps together, you will hear a "click" sound.

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|  | Caution:<br><br>One or both damaged locking clips or one or more missing or damaged O-rings or one or more loose hose connections on the pneumatic plug of the mattress can lead to leakage and thus to unintended use of the system.<br><br>The mattress has to be placed on a suitable bed. The connection of the hose must always be placed at the foot end of the bed. Most surfaces of beds can be used if they don't damage the *ADS eco* mattress. Please make sure that hoses or cells aren't squeezed or damaged by the bed or parts of the bed, or adjustable lying surfaces. |

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|  | You can use the *ADS eco* mattress as an overlay system as well as a replacementsystem. When you use the mattress as a replacement system, make sure that thefoam pocket of the *ADS eco* mattress is filled with a suitable foam with a sufficient height according to the patient weight. Please also pay attention to the minimum distance of upper mattress surface and highest part of the bedrail to make sure that the minimum distance is being considered. |

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|  | The fastening straps must not be attached to the bed frame if this restricts the mobility of the bed in any way. The fastening straps may then only be fastened to the erectable part of the slatted frame. The fastening straps must not connect the slatted frame and the bed frame. Otherwise, there is a risk that the mobility of the slatted frame and possibly the functionality of the bed may be restricted. There is also a risk of damage to the bed and/or the *ADS eco* system. |

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|  | Caution:<br><br>Depending on the bed and support type, ensure compliance with the so-called "bed rail/side rail standard", DIN EN 60601-2-52 (formerly DIN EN ISO 1970) and thus compliance with the minimum distance between the top edge of the bed rail and/or side rail and the top of the patient support. |

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|  | Caution:<br><br>Make sure that the snap locks are intact. If you notice defective snap closures, please replace them immediately. For safety reasons, there are three fastening straps on each side. These ensure that the patient support is held securely on the bed. |

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|  | Caution:<br><br>There must always be a bed sheet between the patient support and the patient. The patient support must not come into contact with the patient's skin or wounds. |

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|  | Caution:<br><br>No liquid may get into the device. Only use the device where it is ensured that no liquid can get inside the device. |

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|  | Caution:<br><br>The device must not be operated in the vicinity of flammable gases. Only use the device where it is ensured that there are no flammable gases in the environment and ambient air. |

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|  | Caution:<br><br>The device must not be covered. There is a risk of heat accumulation in case of covering. |

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|  | Caution:<br><br>For the alarm function working properly, the *ADS eco* must be connected to the mains and be switched on. If the power circuit has been interrupted, the device must be switched on again to ensure that the device functions properly and that the alarm function is active. |

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|  | Caution:<br><br>Before operating and placing the patient onto the system make sure that the system works fine and no damage or leakage has come up. Especially test if CPR connector is closed safely and accurately over all three tubes. |

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|  | Caution:<br><br>The patient may experience side effects when using the medical device. Please take the medical history into account. For example, epilepsies, spasticity or neurological disorders can lead to unwanted reactions on the part of the patient. Observe the patient constantly and closely when using the device. Ask the patient about his condition and consult a physician. |

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|  | Caution:<br><br>Before using the medical device, be sure to check that it is functioning correctly and check the product for damage. If in doubt, do not use the device. |

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|  | Caution:<br><br>The device must not be operated in the area of influence of an MRI / nuclear magnetic resonance tomograph or in the vicinity of the magnetic field. |

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|  | Caution:<br><br>The unit must not be used for X-ray examinations. The patient support may have an influence on the image quality. |

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|  | Caution:<br><br>The device must never come into contact in any form with ignition sources, fire, open light, sparks or similar things, objects, events in order to avoid fires. This also applies to the consumption of tobacco and the lighting of tobacco within a range of 5 m around the system. As the patient support is made of plastic, a general ban on ignition sources of any type design and strength within a distance of 5 m applies here. |

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|  | Caution:<br><br>To protect against infection, only operate the device with protective gloves to protect against possible harmful components on the surface of the device. Clean the device at short intervals and regularly, but at least twice a day. |

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|  | Caution:<br><br>Never place a patient on the patient support before the filling process is complete and the ADS eco indicates that it is ready for use. Due to the pressure relief that is not guaranteed, especially during the early filling process, and the unfilled volume, the patient may fall through. The ADS eco has a data logger which records the runtime, the error code, the set weight, the cycle time and the patient back pressure. The data logger can only be read out by the manufacturer. |

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|  | Caution:<br><br>Operators of ADS eco are asked to monitor frequently the correct usage, in the best case every 30 minutes to one hour to determine that the unit is functioning properly and that there is no fault or damage to the unit. |

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|  | Caution:<br><br>If the patient lying on an ADS eco patient support is not lying centrally on the patient support, or is lying in the embryonic position and only on an upper or lower area of the patient support, depending on the nursing condition, the patient weight setting may have to be corrected, as the patient could otherwise lie on the slatted frame / support. The reason for the possible contact is that the patient in a curved position transfers his weight to a smaller surface, virtually creating a point load. |

# Operational location

The operating location of the device is at the foot end behind the vertical foot section of the bed, on the floor or under the bed at the foot end. These locations are recommended because some patients may find the oscillations and vibrations caused by the device's design disturbing. The transmission of vibrations and noise can be limited in this way. The unit can also be operated in a horizontal position.
**For security reasons it must be ensured that no liquid can get into the device and that the device is not covered by anything!**

# Turning on the device

You connect the *ADS eco* to the mattress as described above.

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|  | You press button **(10)** for approx. 2 seconds, till the light from LED (11) isturned on. |

The mattress can carry patients from 30 kg up to 200 kg.

The patient mattress receptacles are located at the end where the pneumatic connection hose is located. The top end is located at the opposite side. Bottom end of the cover is located where you find the logo "AirMed PLUS".

The top of the cover (deck, cover) is the smooth side; the bottom of the cover contains Jersey-upholstery. The covering is made of polyurethane stretch on the top and a jersey layer on the bottom.

The *ADS eco* starts filling the connected mattress. In doing so, the microprocessor of the ADS is performing a pressure control to determine when the correct pressure for the selected patients weight is reached- shown by permanently illuminated LED (8).

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|  | Caution:<br><br>Never place a patient on the patient support before the filling process is complete and the *ADS eco* indicates that it is ready for use. The patient may lie sore as a result of the pressure not being relieved, especially during the early filling process, and the set volume not being reached yet. |

The mattress consists of nylon and polyurethane coated nylon fabric.

# Choice of operating mode

The *ADS eco* has four operating modes to select:

"Static mode", "Alternating mode", "Nursery mode", "head end up position"

### Static mode

**"static mode"** means that every cell is inflated and the internal pressure is according to the selected patient weight. For 30 kg internal pressure will be approximately 14 mmHG, for 200 kg internal pressure will be approximately 62 mmHg.

### Nursery mode

The LED (7) is illuminated when this mode is chosen.

By pressing button (6) the function "static mode" of the *ADS eco* is selected and now operates. You can increase the internal pressure of the mattress by pushing button (3) to a maximum. "Nursery mode" means, all cells will be inflated with maximum pressure.

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|  | From nursery mode the system will not automatically turn into other modes. Operators need to turn into other modes manually and decrease the internal pressure by pressing button (2) to a lower value. |

### Alternating mode

The LED (8) is flashing when this mode is being chosen and when the mattress is currently alternating. One cycle time for this three way system will take approximately 11 minutes.

### Head end up position

When pressing the button (5), the pressure in the mattress will be increased in case the operator wants to lift the head end up. When the head end is lifted up, the forces squeezing the mattress will be higher. In order to avoid that the patient will sit on the ground of the mattress, internal pressure needs to be increased. This mode only works for approximately 30 minutes. Choosing this mode, the internal pressure will be approximately 52-60 mmHG.

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|  | Head end up - mode will only be available for approximately 30 minutes. After that time the system turns into normal mode again. If patient is asked to sit instead of lying in the bed, please check for other products for sitting only. |

# Zero-pressure positioning

Individual cells can be removed to position certain body regions pressure-free in the "Static" operating mode. To do this, remove the cover of the patient support, loosen the pushbuttons of the desired cell on the left and right of the support base and pull off the hose connection of the cell at the hose system in the support base. Now use the sealing cap (item number 10-8007) to close the opening in the hose system to prevent leakage and thus also an alarm. Pull the detached cell sideways out of the cell guiding and reattach the cover to the support base.

If the cell removed for pressure-free positioning is not filled for the duration of the interval cycle, this can result in pressureless positioning areas that are twice as large and unfilled. In this case, the patient could sink through to a hard surface.

## Locking and unlocking the panel

The panel will lock automatically after approximately 5 minutes. When panel is locked, LED (12) is illuminated permanently in blue.

You will enable or disable the panel lock by pressing button **(4).**

## Setting the weight of the patient

Setting the weight of the patient is possible in all modes.

The weight of the patient is set by key **(2) and (3)**. The steps are based on full kilograms. For a less weighing patient press (2) and for a higher weighing patient press (3). If you keep the button pressed, the change will be happen in steps of 10 kg (more rapidly).

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|  | Caution:<br><br>The internal pressure values and software protocols of *ADS eco* are dedicated to a very good pressure relief. For this AirMed PLUS GmbH used the guideline for tests determined by the German GKV, published by the dome of the legal health insurance funds (GKV Union-Germany). In this test it is assumed that a patient is positioned in central back position on the mattress and that the patient possesses all limbs.<br><br>**If the patient will be placed on to *ADS eco* mattress in a different way than lying on the back, e.g. lying on the side, the patient forces more normal pressure to the mattress because he decreases the touching area. A decreased touching area means giving more force to the mattress = sinking deeper. To avoid touching the ground, please always double-check if the pressure - that means choosing the proper patient weight - is sufficient to hold the patient away from the mattress ground. The higher the patient weight the higher the internal pressure.** |

## Turning off the device

To turn off the device press button **(10)** for 2 seconds. Button (10) is not working when the panel is locked. Please unlock the panel by pressing button(4) first to disable the device.

# Alarms

The *ADS eco* is equipped with an optical and audible alarm. Early warning is monitored by the microcontroller. In case of device issues the optical alarm will be shown in the display with LED (8) flashing AND an alarm beep ringing. Leakage alarm will occur after a couple of minutes to avoid lying sore.

If a leakage alarm has come up please check following things first:

- check for leakage in the pneumatic system
- check CPR
- check if mattress is connected properly
- check if leakage is in one of the cells or in connection hose or in the device
- is an AD-mattress connected?
- is the CPR-vent open?
- are one or more cells are removed and the tube connection is still open and not closed by a closing-tube?
- if hoses are fastened with the pneumatic plug
- if O-rings are defect or missing entirely up to the pneumatic plug
- if the mattress has a hole or a crack
- check for other leaks.

A leakage alarm is an audible alarm and always comes up together with a visible alarm.

If you've checked all possible causes and you cannot find the cause, please contact our service department.

If an optical alarm for device issues occurs, please disconnect the device from the power supply and don't use the device anymore. Please contact our service department.

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|  | Caution:<br><br>Alarm-function will only work when *ADS eco* is connected to the electricity supply system. If the electricity supply system has been switched off or has failed or the *ADS eco* was temporarily switched off, you have to turn on the *ADS eco* again to make sure that the alarm system of the *ADS eco* will work properly. |

# Cleaning / Disinfection

The device can be wipe-disinfected with a suitable disinfectant to kill germs and bacteria. AirMed PLUS GmbH uses the product ANTISEPTICA poly-alcohol skin colorless antiseptic for this purpose.

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|  | Attention: No liquid must get into the device. |

The patient support and the cover can be disinfected by the user. The patient support can be wipe-disinfected with a suitable disinfectant to kill germs and bacteria, e.g. with the above-mentioned agent. The patient support including the cover or the cover alone can also be washed chemo-thermally at 60°C in a washing machine by the user using a suitable detergent to kill germs and bacteria, e.g. ELTRA from Henkel/Ecolab. Please observe the symbols on the patient support insert and the cover.
The patient support and the cover must not be washed at temperatures hotter than 65°C as they may otherwise be damaged.
The unit and patient support are intended for reuse. The unit and the patient support must be cleaned and disinfected before each reuse.
The ADS eco system must be cleaned differently depending on the degree of soiling and infection. In the case of light soiling without germ contamination on the surface of the patient support, wipe disinfection and complete removal of the soiling is sufficient. For technically understandable reasons, the unit can only be wipe-disinfected and must not be immersed in liquids. It is possible and advisable to cover the operating surface with a transparent plastic film, but the cover must not cover the entire unit, as otherwise a build-up of heat may occur and/or the unit will no longer receive air to perform its function. The control surface is the most touched part of the whole system.

In the event of contamination of the patient support with dirt and/or germs, the entire patient support must be reprocessed chemothermally. For this purpose, we recommend a chemo-thermal washing process of all components of the patient pad over a period of at least one hour (preferably 2 hours), at a temperature of 65°C - 70°C and the use of the "ELTRA" detergent from Ecolab in a disinfection wash cycle.
(For product compatibility with other detergents, cleaning agents and/or disinfectants used in the corresponding (your) facility, please consult AirMed PLUS GmbH).

For chemothermal reprocessing, the cover is separated from the patient support by opening the zipper. (If this were not done, the cleaning water would have difficulty reaching the outside of the air cells and the inside of the base, making it difficult to clean these components). The patient support is closed at the air unit connection/pneumatic connector with the closure located on it.
The CPR outlet must also be closed. The patient support and the separate cover must be washed separately. After washing, both parts must be hung up to dry. The use of a dryer is not permitted, as this may damage the mattress. Residual water must be removed in any case.

If the patient support is contaminated with such germs and the effectiveness of the detergent, cleaning agent and/or disinfectant used is called into question, and/or if the patient support is contaminated with new, mutated germs about which the manufacturer of the detergent, cleaning agent and/or disinfectant has not yet provided any information, we recommend proper disposal of the contaminated patient support in order to avoid cross-contamination.
In any case, the performance of the detergent, cleaning agent and/or disinfectant used must always be taken into account with regard to its ability to remove the corresponding soiling and/or contamination.
Attention, clear warning: deviations from these instructions may have a direct impact on the degree of cleanliness, the service life to the effectiveness of the product.

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|  | Caution: To protect against infection, only operate the device with protective gloves to protect against possible harmful components on the surface of the device. Clean the device at short intervals and regularly, but at least twice a day. |

## Filter

The *ADS eco* features a dust filter on the back of the device. The dust filter must be changed at least once a month, depending on the environment even several times.
For example: At the latest if the filter is brown or green colored. You buy the dust filter as a set of 10 pieces at the Service Center of AirMed PLUS (item number 99-1129).

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|  | Attention:<br><br>Dust and contaminated air, especially nicotine, clog the filter very quickly. As a result, there is a risk that the built-in pump will not be able to fill the patient support as intended, the patient may pass through and/or the unit may be damaged. In addition, due to the small particle size, nicotine, for example, can enter the interior of the unit through housing slots and joint edges and cause contamination there. Therefore, avoid operating the device in a contaminated environment and do not smoke in the vicinity of the device. Otherwise, the warranty will be voided. |

# Disposal

Dispose of the medical device properly via a suitable disposal company. If the device and / or the patient support is contaminated, select a disposal company that can properly dispose of the product depending on the degree of contamination.

# Life Time /Life Span

The service life depends on several parameters, such as the type or frequency of use and cleaning, mechanical, chemical and physical influences, among others. The service life is thus specified between 5 and 12 years. The service life specification must not be compared with the guarantee and / or warranty specifications.

# Storage and transport conditions

Ensure that the product is stored and transported dry, protected from dust and wind, protected from direct sunlight, between 5°C and 45°C, at a relative humidity between 50% and 90%.

# Contra-indications

Alternating pressure systems transmit vibrations due to their design and change the patient's support profile in alternating pressure mode. This mobilization can lead to health problems in certain patients.

Contraindications to the use of alternating anti-decubitus systems include spinal fractures, fractures in areas and sites of the patient where alternating air cells negatively affect

healing and do not allow for desired fixed positioning of the patient's fracture site, and patients who may not be mobilized. If unsure, consult a physician to be certain whether alternating pressure operation may be contraindicative to the patient's individual ecoal picture. Perceptual disturbances can also occur in the alternating pressure operating mode.

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|  | For contraindications please ask the patient or the responsible nurse for the reaction of the patient. Please focus on the patient reactions very carefully and immediately from the first minute of using *ADS eco* to avoid any harm to the patient. |

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|  | Keep existing bedsores away from touching the mattress in anyway to keep the pressure as low as possible referring to the injured areas and areas of bed sores. |

# Maintenance

For the *ADS eco*, repeat testing of electrical safety for electrical equipment is mandatory. The intervals for this depend on the previous year's result of the test at the operator's premises. For the sake of simplicity, we recommend an annual inspection. During the inspection, it must be taken into account that the ADS eco has no electrically conductive part on the outside of the housing that is connected to the protective conductor.
For the *ADS eco*, maintenance is prescribed at two-year intervals. However, annual maintenance is recommended as the ADS eco is a high quality medical device whose service life will be extended with regular inspection and preventive measures, thus maintaining the performance of the product.
Repairs and maintenance may only be carried out by persons companies that have been trained for this purpose by the manufacturer. The training of the companies and persons are confirmed by the manufacturer by certificate.

**Declaration of conformity**

The manufacturer: AirMed PLUS GmbH,
Harpener Feld 34
44805 Bochum
Deutschland

Declares herewith, that the following medical device:

Product name: ADS *eco (10-1005), EAN* 4260675870605

conforms to the requirements of the European Medical Devices Regulation (MDR) 2017/745, the ADS *eco* corresponds to risk class 1 (Rule 13 of Annex VIII).

Applied standards:

DIN EN 980
DIN EN 1041
DIN EN ISO 14971
DIN EN 60601-1
DIN EN 60601-1 -1, -2, -4, -6,
DIN EN ISO 20342-1

Bochum,
02.03.2022

Date

CEO AirMed PLUS GmbH

CE

Service for the *ADS eco*:

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